Clinical Policy Title: Glaucoma testing

Clinical Policy Number: 10.01.04

Effective Date: February 1, 2017
Initial Review Date: January 18, 2017
Most Recent Review Date: January 11, 2018
Next Review Date: January 2019

Related policies:
CP# 10.03.03 Canaloplasty and viscocanalostomy in treatment of glaucoma
CP# 18.01.02 Telehealth

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s 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 Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state and federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s 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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of glaucoma testing to be clinically proven and, therefore, medically necessary when the following criteria are met:

- 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 (AAO, 2010; EGS, 2008).

Limitations:

Select Health of South Carolina considers the use of routine glaucoma screening of the general population to be investigational/experimental and, therefore, not medically necessary.
Select Health of South Carolina considers the use of glaucoma testing to be 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 (USPSTF, 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 3 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 (GRF, 2017a). A family history of glaucoma increases risk of the disorder by four to nine times (GRF, 2017b).

Children (typically under age 1) 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 (GRF, 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 (GRF, 2017d).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on December 11, 2017. Search terms were: “glaucoma testing” and “glaucoma screening.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**
Guidelines for glaucoma testing are bound to the traditional methods of diagnosis (Ou, 2011). The American Academy of Ophthalmology (AAO, 2010) and South East Asia Glaucoma Interest Group (SEAGIG, 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 (EGS, 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 contemporary assessment of the value of screening of the general population for glaucoma from the U.S. Preventive Services Task Force (USPSTF, 2013) found no direct evidence on the benefits of screening. The USPSTF 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. However, the USPSTF found 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.

Standard automated perimetry has been commonly used to diagnose glaucoma. 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 (Turalba, 2010).

An early systematic review from the United Kingdom documented glaucoma screening tests with a specificity rate of 85 percent 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 (Burr, 2008).

Another systematic review from the United Kingdom of 40 studies (n=48,000) assessed nine tests, although most were reported by only a few studies. No clear patterns of sensitivity and specificity emerged, and data were deemed of limited quality, and the review could not identify a superior test (Mowatt, 2008).

The Agency for Healthcare Research and Quality 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 (Ervin, 2012).

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. 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 percent of cases (sensitivity 70 percent), and would incorrectly refer 5 percent without glaucoma (specificity 95 percent). Accuracy was relatively consistent by device (SCHTA, 2015; Michelessi, 2015).

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. 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) (Azuara-Blanco, 2016).

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 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 percent and 79.0 percent (Thomas, 2014).

There is no conclusive medical evidence that genetic testing for glaucoma is impactful in influencing treatment outcomes or reducing glaucoma-related blindness yet. The scientific research for a link between genetics and glaucoma is an emerging body of work (Mauri, 2016; Liu, 2016; Al-Shahrani, 2016; Khawaja, 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.

Policy updates:

A total of four guidelines/other and 10 peer-reviewed references were added to this policy in December 2017.

Summary of clinical evidence:
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fallon (2017)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Accuracy of diagnosing glaucoma, by device</td>
<td>- Meta-analysis of 86 articles on ability to detect glaucoma.</td>
</tr>
<tr>
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<td>- Odds ratios for detecting glaucoma were 29.5 for optical coherence tomography, 18.6 for GDx, and 13.9 for Heidelberg retinal tomography.</td>
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<td>- Optical coherence tomography is most accurate means of testing.</td>
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<tr>
<td>Ahmed (2016)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Accuracy of diagnosing glaucoma, relatively new devices</td>
<td>- Meta-analysis of relatively new techniques of glaucoma testing searched 2,474 articles</td>
</tr>
<tr>
<td></td>
<td>- Diagnostic odds ratio for frequency doubling technology was 57.7, exceeding blue on yellow perimetry (46.7), optical coherence tomography (41.8), GDx (32.4), and Heidelberg retina tomography (17.8).</td>
</tr>
<tr>
<td></td>
<td>- Frequency doubling technology is most accurate means of testing, but several devices have high accuracy.</td>
</tr>
<tr>
<td>Michelessi (2015)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Accuracy of diagnosing glaucoma by device, sensitivity and specificity</td>
<td>- Systematic review of 106 studies (n=16,260 eyes), assigned to cases and controls</td>
</tr>
<tr>
<td></td>
<td>- Goal was to assess 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.</td>
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<tr>
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<td>- 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 percent of cases (sensitivity 70 percent), and would incorrectly refer 5 percent without glaucoma (specificity 95 percent).</td>
</tr>
<tr>
<td></td>
<td>- Accuracy was relatively consistent by device.</td>
</tr>
<tr>
<td>Ou (2011)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>A critical appraisal and comparison of the quality and recommendations of glaucoma clinical practice guidelines</td>
<td>- All published guidelines on glaucoma testing recommend slit-lamp biomicroscopy with stereoscopic visualization of the optic nerve, as well as direct ophthalmoscopy.</td>
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<td>- EGS defines a threshold of 21 mm intraocular pressure peak in the untreated eye as diagnosis of primary open-angle glaucoma (POAG).</td>
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<td></td>
<td>- AAO and SEAGIG guidelines do not define an intraocular pressure requirement in the diagnosis of POAG.</td>
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<td></td>
<td>- AAO and EGS guidelines address age of onset; SEAGIG does not.</td>
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<td></td>
<td>- AAO and SEAGIG guidelines specify that POAG can only be diagnosed in the absence of other causes.</td>
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<tr>
<td></td>
<td>- AAO, EGS, and SEAGIG require different descriptions of optic nerve findings:</td>
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<tr>
<td></td>
<td>o AAO requires only minimal documentation of neuropathy.</td>
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<td></td>
<td>o The EGS guidelines illustrate various optic nerve findings with drawings and detailed text.</td>
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<tr>
<td></td>
<td>o SEAGIG guidelines not only provide descriptive guidelines on detecting glaucomatous optic neuropathy but also include an appendix with illustrative optic nerve photographs (non-stereoscopic).</td>
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</tbody>
</table>
AAO and EGS recommend stereoscopic disc photography or computer-based image analysis (e.g., optical coherence tomography) of the optic nerve and retinal nerve fiber layer.

References

Professional society guidelines/other:


Peer-reviewed references:


CMS National Coverage Determinations (NCDs):

No NCDs 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).


Local Coverage Determinations (LCDs):

No LCDs 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 percent 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.

Medicare.gov. Local coverage article: glaucoma screening. Medicare.gov website: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=53495&ver=6&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=glaucoma&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAACA%3d%3d&. Accessed December 11, 2017.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
<td></td>
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<tr>
<td>92100</td>
<td>Serial tonometry with multiple measurements of ocular pressure over an extended period of time, with interpretation and report the same day</td>
<td>Single episode tonometry is a component of the ophthalmological service or E/M service</td>
</tr>
<tr>
<td>92133</td>
<td>Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report unilateral or bilateral; optic nerve</td>
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<tr>
<td>92134</td>
<td>Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report unilateral or bilateral; retina</td>
<td></td>
</tr>
<tr>
<td>92140</td>
<td>Provocative tests for glaucoma, with interpretation and report, without tonography</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>ICD 10 code</th>
<th>Description</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>E08-E13.9</td>
<td>Diabetes mellitus</td>
<td></td>
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<tr>
<td>H40.00-H42</td>
<td>Glaucoma</td>
<td></td>
</tr>
<tr>
<td>Z83.511</td>
<td>Family history of glaucoma</td>
<td></td>
</tr>
<tr>
<td>HCPCS Level II code</td>
<td>Description</td>
<td>Comments</td>
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<tr>
<td>G0117</td>
<td>Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist</td>
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<tr>
<td>G0118</td>
<td>Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist</td>
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