Clinical Policy Title: Canaloplasty and viscocanalostomy in treatment of glaucoma

Clinical Policy Number: CCP.1140

Effective Date: April 1, 2014
Initial Review Date: October 15, 2014
Most Recent Review Date: October 2, 2018
Next Review Date: October 2019

ABOUT THIS POLICY: 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

AmeriHealth Caritas considers the use of canaloplasty in the treatment of glaucoma to be clinically proven, and therefore, medically necessary (Lewis, 2011; Lin, 2016; National Institute for Health and Care Excellence, 2017; Zhang, 2017).

AmeriHealth Caritas considers the use of viscocanalostomy in treatment of glaucoma to be clinically proven, and therefore, medically necessary (Chai, 2010; Cheng, 2010, 2011; Eldaly, 2014; Hondur, 2008).

Limitations:

All other uses of canaloplasty and viscocanalostomy are not medically necessary.

Alternative covered services:

- Approved pharmacotherapy as ordered by primary care provider and/or specialist.
• Approved conventional treatments (e.g., trabeculectomy).

Background

Glaucoma describes a complex group of eye diseases characterized by damage to the optic nerve, leading to irreversible vision loss and blindness. Glaucoma affects more than 60 million people worldwide, and approximately 4 million people in the United States. Glaucoma usually begins with subtle loss of peripheral vision and, if left undiagnosed and untreated, will eventually progress to complete blindness. It is estimated that 12.3 percent of all cases of blindness globally are due to glaucoma, making it the second leading cause of blindness after cataracts.

Because glaucoma is treatable, and because the visual impairment from glaucoma is irreversible, early detection of the disease is critically important. There are several types of glaucoma, all associated with optic nerve damage, leading to visual impairment. The most common type is primary open-angle glaucoma, thought to account for up to 75 percent of all cases of glaucoma diagnosed worldwide and up to 90 percent of glaucoma diagnosed in the United States. Prevalence of primary open-angle glaucoma in adults over age 40 in the United States is estimated to be approximately 2 percent.

Primary open-angle glaucoma is usually, though not always, associated with increased intraocular pressure, which can potentially damage the delicate fibers of the optic nerve head, located at the back of the eye. A fluid, known as aqueous humor, is produced in the eye by the ciliary body, located behind the iris. Most of this fluid flows through the pupil and drains away at the open angle between the cornea and the iris. The aqueous humor then passes through a porous tissue, known as the trabecular meshwork, and into a collector channel known as Schlemm's canal.

The eye keeps its shape and is maintained by the constant production and drainage of the aqueous humor. Open-angle glaucoma describes a condition in which there is no physical obstruction of the drainage angle of the eye, but there is characteristic damage to the optic nerve, and the presence of visual field loss (Foster, 2002). The early stages of primary open-angle glaucoma are often asymptomatic, and both eyes are usually affected, though typically asymmetrically. Increased intraocular pressure is one of the main risk factors for primary open-angle glaucoma, although it is not a requirement for diagnosis, and primary open-angle glaucoma often occurs in patients with intraocular pressures within the normal range. Other risk factors for primary open-angle glaucoma include older age, family history, African or Latino ancestry, and Type 2 diabetes.

Despite the fact that not all patients diagnosed with primary open-angle glaucoma have elevated intraocular pressure, current evidence suggests that reducing intraocular pressure has a significant preventive effect on the progression of the disease, irrespective of whether intraocular pressure is abnormal at diagnosis. Medications (eye drops), laser treatments, and surgery can all be used to lower intraocular pressure, which is currently the only known modifiable risk factor for primary open-angle glaucoma.
Current options for medical therapy include prostaglandin analogs, alpha-adrenergic agonists and parasympathomimetic agents, which all work by increasing fluid outflow; and beta-blockers and carbonic anhydrase inhibitors, which act to decrease aqueous production (American Academy of Ophthalmology Glaucoma Panel, 2010; Vass et al., 2007). If a single medication does not lower intraocular pressure to the target level, alternate therapies may be selected, or a combination of agents may be appropriate. Side effects are generally minimal with topical medication; however, adequate treatment requires a high level of adherence to prescribed therapy, and often this is not achieved). In addition, instilling eye drops correctly may be difficult for some patients, and may become more difficult as their glaucoma worsens).

Laser treatment is another alternative for lowering intraocular pressure in primary open-angle glaucoma patients. The most common procedure is laser trabeculoplasty, which uses laser light directed at the trabecular meshwork to reduce resistance to aqueous humor outflow. Although many patients respond initially to this type of therapy, the effect may be lost over time, especially in younger patients. Another laser intervention is the cyclophotocoagulation procedure; this technique decreases aqueous production by damaging the ciliary body with laser energy (Chen et al., 1997). Laser cyclophotocoagulation may be useful in patients with advanced cases of primary open-angle glaucoma for whom other medical and surgical treatments have failed.

The most common incisional surgical treatment for primary open-angle glaucoma is a type of filtration surgery known as trabeculectomy. In this technique, a small portion of the trabecular meshwork, or surrounding tissue, is removed, creating an alternative path for the release of aqueous humor into an outer cyst (or bleb). Antifibrotic agents, such as mitomycin-C and 5-fluorouracil, may be used intraoperatively and postoperatively, to reduce scarring and prevent closure of the new channel.

Canaloplasty procedures are increasing over time. From 2007 to 2012, the number of Medicare beneficiaries undergoing the surgery rose from 161 to 2,426. However, this number is still far below related procedures. For example, 142,682 trabeculoplasties were performed on Medicare patients in 2012 (Arora, 2015).

The canaloplasty procedure (iTrack™ 250A Canaloplasty Microcatheter; iScience Interventional Inc.) is a nonpenetrating surgical technique that takes advantage of the eye’s natural drainage system to reduce intraocular pressure in patients with primary open-angle glaucoma (Lewis, 2007). In 2008, the iTrack received U.S. Food and Drug Administration clearance for the indication of “catheterization and viscodilation of Schlemm’s canal to reduce intraocular pressure in adult patients with open angle glaucoma” (Keamey, 2006).

During the procedure, which can be done under local or general anesthetic, a flap is made in the sclera, and the entrance to the canal of Schlemm is exposed. A microcatheter with an illuminated tip is introduced into the canal and advanced around its entire circumference. As the catheter is advanced, viscoelastic fluid is injected to dilate the canal. Once the distal tip of the catheter emerges after circumferential catheterization, a suture is attached to the tip of the catheter and retracted, pulling the
suture into the canal. The suture is then cut from the microcatheter and tied in a loop, putting tension on the inner wall of the canal and distending the trabecular meshwork.

Viscocanalostomy is a relatively new technique developed for glaucoma surgery and was first proposed in 1991. It is a procedure used to treat glaucoma that involves surgical incisions and injection of a viscous, elastic material into the eye. The goal of this procedure is to reduce intraocular pressure by creating a channel that allows excess fluid to drain from the eye. Viscocanalostomy can be performed under peribulbar or retrobulbar anesthesia, and should be performed by an ocular surgeon who has been specifically trained in this technique.

During this procedure, a limbal-based, half-thickness scleral flap is dissected deeply into clear cornea and a second flap is dissected near the ciliary body. Schlemm’s canal is unroofed by gentle pulling on the scleral flap, and by simultaneously peeling the fibrotic lining from the bottom of the canal and the juxtacanalicular trabecular meshwork. After the membrane is cleaved from the cornea to create a corneal “window,” the inner scleral flap is excised. A cannula is then inserted in Schlemm’s canal, the canal is filled with sodium hyaluronate, the cannula is removed and the flaps are sutured closed (Hayes, 2003).

Viscocanalostomy involves the additional step of injecting high-viscosity fluid into Schlemm's canal to encourage fluid egress (Stegmann et al., 1999). The complication rate for viscocanalostomy is lower than for trabeculectomy; however, viscocanalostomy is not as effective in lowering intraocular pressure (Carassa et al., 2003; Yalvac et al., 2004). Other surgical procedures that may be used in primary open-angle glaucoma patients include trabeculotomy, insertion of trabecular meshwork stents, and insertion of aqueous shunts. A meta-analysis conducted by Cheng et al. (2009) concluded that viscocanalostomy and deep sclerectomy were less effective than trabeculectomy in the treatment of open-angle glaucoma. However, viscocanalostomy and deep sclerectomy were associated with fewer complications than trabeculectomy.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 15, 2018. Search terms were “glaucoma,” “canaloplasty,” and “viscocanalostomy.”

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**

Several guidelines have been published on efficacy of various procedures for open-angle glaucoma. An updated guideline from Britain’s National Institute for Health and Care Excellence (2017) states that “current evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit.” This replaces an earlier National Institute for Health and Care Excellence (2008) guideline stating that canaloplasty should only be performed in research settings. A 2009 guideline, which stated “the only established method of treating glaucoma is lowering intraocular pressure,” concluded there is insufficient evidence comparing all procedures to the more established trabeculectomy (Canadian Ophthalmological Society Clinical Practice Glaucoma Guideline Expert Committee, 2009).

A 2015 American Academy of Ophthalmology guideline provided nine references given for viscocanalostomy, eight of which were published from 2001 to 2006; the other was from 2009. Only two references were given for canaloplasty. In one, reductions in average intraocular pressure for canaloplasty in 157 eyes was significant (23.8 to 15.2 mm Hg) three years post-operative (Lewis, 2011). In the other, the 46 eyes undergoing trabeculectomy had an intraocular pressure reduction of 46 percent, close to significantly higher than the 32 percent reduction in the 33 eyes undergoing canaloplasty (Ayyala, 2011). The guideline also stated that “no randomized clinical trial comparing trabeculectomy and canaloplasty exists” (Prum, 2015).

A systematic review for the U.S. Preventive Services Task Force concluded that, compared with viscocanalostomy or deep sclerectomy, trabeculectomy “produces more hypotony, hyphema, shallow anterior chambers, cataract, and choroidal detachment,” and that intraocular glaucoma surgery presents an increased risk for cataract and a rare but serious intraocular infection, compared with laser trabeculoplasty and medical treatment (Boland, 2013). No studies were found that compared visual impairment or patient-reported outcomes among glaucoma treatments.

The literature contains eight meta-analyses and/or systematic reviews involving efficacy of canaloplasty and/or viscocanalostomy; a summary is given here:

1. The percent of cases (3 year post-operation) with intraocular pressure < 21 mm Hg was 48.6 and 51.1 for deep sclerectomy and viscocanalostomy; 67.1 and 38.6 percent with anti-metabolites (Hondur, 2008).
2. In 10 trials of 458 eyes (397 patients), trabeculectomy had greater reductions in intraocular pressure than did viscocanalostomy, but trabeculectomy had more post-op adverse events (Chai, 2010).

3. In a meta-analysis of 17 randomized clinical trials, viscocanalostomy was significantly less effective in reducing intraocular pressure than trabeculectomy, but caused fewer complications (Cheng, 2010).

4. In a meta-analysis of 29 randomized clinical trials (n=1287), two years after surgery, intraocular pressure reductions were significantly lower in viscocanalostomy vs. trabeculectomy (30.2 vs. 45.6 percent), with lower complete success rates (22.7 vs. 47.6 percent) (Cheng, 2011).

5. A systematic review/meta-analysis of 18 articles found trabeculectomy had significantly greater reductions in intraocular pressure than did non-penetrating surgery, with more complications (Rulli, 2013)

6. A Cochrane review of five studies (n=311 eyes) found significantly lower odds of success for viscocanalostomy vs. trabeculectomy, with relatively few complications (Eldaly, 2014).

7. A meta-analysis of four studies (n=215 eyes) found statistically greater reductions in intraocular pressure for trabeculectomy vs. canaloplasty, and an insignificantly greater improvement in complete or qualified success rates for trabeculectomy (Lin, 2016).

8. A meta-analysis comparing the safety and efficacy of canaloplasty and trabeculectomy included 28 studies (Zhang, 2017). The main outcome was that while trabeculectomy resulted in a greater improvement than canaloplasty, it was associated with a higher incidence of complications. Two of the included studies were randomized clinical trials, while 15 were retrospective and 11 were prospective studies.

Despite the superior results of trabeculectomy to reduce intraocular pressure compared to canaloplasty or viscocanalostomy, canaloplasty has been reported to be performed in glaucoma patients with early to moderate disease and in combination with cataract surgery (Cagini, 2016).

**Policy updates:**

2016 and 2017: New references and findings were added. 2018: One new peer-reviewed reference was added. Policy ID changed from 10.03.03 to CCP.1140.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Zhang (2017)</td>
<td>A system review and meta-analysis of canaloplasty outcomes in glaucoma treatment in comparison with trabeculectomy.</td>
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</tbody>
</table>

**Key points:**

- A total of 28 studies (n=1,498 eyes, 78% with primary open-angle glaucoma) were included and there were multiple sub-analyses.
- Main findings: Trabeculectomy showed higher improvement but had higher complications.
- In comparison of intraocular pressure post-canaloplasty (total 106) versus post-trabeculectomy (total 148), analysis of 4 studies found a mean difference of -3.65 (95%
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| trabeculectomy | confidence interval (CI) -6.42, -0.88; mean difference in antiglaucoma medications was -0.36 (CI -0.91, 0.19) (both favoring canaloplasty). Trabeculectomy also showed better control of intraocular pressure at 12 months (3.61% mmHg higher reduction (CI 1.69, 5.53). At 12 months, there was no significant difference in antiglaucoma medication reduction between the two procedures or in the complete or qualified success rates.  
• In terms of complications, while canaloplasty showed a higher rate of hyphem (which could be an indication of efficacy of canaloplasty), hypotony and choroidal effusion/detachment were less common in canaloplasty compared to trabeculectomy. Suprachoroidal hemorrhage was only associated with trabeculectomy. |
| Lin (2016) | Key points:  
• Meta-analysis of four studies (n=215 eyes; 100 underwent canaloplasty, 115 underwent trabeculectomy)  
• Reduction in intraocular pressure was significantly greater for trabeculectomy  
• Proportions of complete and qualified successful cases, and reduction in anti-glaucoma medications not significantly different between two groups  
• Adverse events significantly lower for canaloplasty group |
| Eldaly (2014) | Key points:  
• Meta-analysis, five studies, 311 eyes (247 patients).  
• One hundred sixty trabeculectomy, 101 sclerectomy, 50 viscocanalostomy.  
• Odds of success lower in viscocanalostomy.  
• No difference in achieving target intraocular pressure.  
• Trabeculectomy has more complications. |
| Rulli (2013) | Key points:  
• Meta-analysis, 18 articles, six-month post-op comparing trabeculectomy vs. other procedures.  
• Trabeculectomy is most effective procedure for reducing intraocular pressures, has higher incidence of complications. |
| Cheng (2011) | Key points:  
• Meta-analysis of 29 randomized clinical trials (n=1287)  
• Two years after surgery, reductions in intraocular pressure deep sclerectomy (35.2%) and viscocanalostomy (30.2%) were significantly less than trabeculectomy (45.6%)  
• Complete success rates in two years were significantly higher for trabeculectomy (47.6%), vs. deep sclerectomy (35.4%) and viscocanalostomy (22.7%)  
• More complications occurred after trabeculectomy than the other two procedures |
| Cheng (2010) | Key points:  
• Meta-analysis of 17 randomized clinical trials  
• Viscocanalostomy and deep sclerectomy were significantly less effective than |
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<tr>
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| Chai (2010) | **Key points:**  
- Systematic review/meta-analysis of non-penetrating glaucoma surgery with trabeculectomy, both with mytomycin C added  
- Eight clinical trials, four cohort and four randomized (n=459 eyes)  
- Non-penetrating surgeries had insignificantly greater reductions in intraocular pressure  
- Non-penetrating surgeries had significantly fewer cases achieve target |
| Hondur (2008) | **Key points:**  
- Meta-analysis of effectiveness of non-penetrating glaucoma surgeries (mean follow up three years)  
- Percent cases with intraocular pressure < 21 mm Hg was 48.6% and 51.1% for deep sclerectomy and viscocanalostomy  
- Percent cases with intraocular pressure < 21 mm Hg was 67.1% and 38.6% for deep sclerectomy with anti-metabolite and viscocanalostomy with anti-metabolite or implant |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as the writing of this policy.

**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.

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