CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Viscocanalostomy and Canaloplasty**

Effective Date **3/15/2011**
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Coverage Policy Number **0035**

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Corneal Pachymetry
Retinal Imaging for Diabetic Retinopathy

Coverage Policy

CIGNA does not cover viscocanalostomy (including phacoviscocanalostomy) or canaloplasty for any indication, including the treatment of glaucoma, because each is considered experimental, investigational or unproven.

General Background

Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid build up. The increased pressure can lead to optic neuropathies characterized by visual field loss and structural damage to the optic nerve fiber. If left untreated, glaucoma can result in partial or complete visual impairment. Currently, intraocular pressure (IOP) is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision.

In most cases, oral or topical medication is the first treatment of choice. For patients who are unwilling or unable to rely on available medications, surgical treatment, such as laser trabeculoplasty and trabeculectomy, may be an option. Although laser trabeculoplasty reduces IOP initially, its effects diminish over the course of a few years, and repetition of the procedure may not be beneficial. Trabeculectomy, an invasive procedure, is the current standard surgical technique for reduction of IOP, but it can result in extremely low IOP, causing ocular damage.

To provide the benefits of trabeculectomy (I.e., normalization of IOP) but avoid the postoperative complications (e.g. hypotony, flat anterior chamber, and choroidal detachment), nonpenetrating surgical procedures, such as viscocanalostomy and canaloplasty, have been proposed as an alternative treatment option for patients with open-angle glaucoma (OAG). Viscocanalostomy involves creating a scleral reservoir and an injection of a viscoelastic biocompatible polymer to open the ostia of the canal. This opening allows passage of fluid from the anterior chamber into the canal which lowers the IOP. Unlike trabeculectomy, viscocanalostomy avoids full-thickness penetration into the anterior chamber of the eye. Canaloplasty is a nonpenetrating procedure, similar to viscocanalostomy, aimed at lowering the IOP by permanently stretching the trabecular meshwork and restoring the natural drainage of fluid out of the eye. Compared to viscocanalostomy, canaloplasty involves dilation of Schlemm's canal and placement of a suture that is proposed to ensure that the entire length of the canal stays open (Goldberg, 2006; Koerber, 2007; National Institute for Health and Clinical Excellence [NICE], 2008).

Viscocanalostomy is also proposed for use in conjunction with phacoemulsification (i.e., the removal of lens nucleus within the lens capsule by breaking up the lens into tiny pieces for extraction) during cataract surgery. The combination of cataract surgery and viscocanalostomy is called phacoviscocanalostomy and is proposed for use in the place of phacotrabeculectomy. The combined surgery is used for patients who require surgical intervention for the treatment of cataract and glaucoma. Compared to cataract surgery alone, phacoviscocanalostomy is proposed to provide better long-term control of IOP, protection from postoperative IOP spikes and prevention of late-failure trabeculectomy (Kobayashi and Kobayashi, 2007; Shoji, et al., 2007; Park, et al., 2006; Wishart, et al., 2006). The evidence in the published peer-reviewed literature does not support viscocanalostomy, canaloplasty or phacoviscocanalostomy for the treatment of glaucoma.

Literature Review – Viscocanalostomy

Randomized controlled trials have reported that viscocanalostomy is not clinically comparable to trabeculectomy, the standard surgical procedure for the treatment of glaucoma, in reducing and maintaining lower IOP values. Overall, significantly better reductions in IOP were seen following trabeculectomy and in some cases, with less repeat treatments needed.

Chai and Loon (2010) conducted a meta-analysis of ten randomized controlled trials (n=458 eyes/397 patients) to compare the outcomes of viscocanalostomy to trabeculectomy mainly for the treatment of primary (n=371) or secondary (n=75) open-angle glaucoma. The authors compared the postoperative mean intraocular pressure (IOP), mean number of antiglaucomatous medications, as well as adverse events. Follow-ups ranged from six month to four years. At six, 12, and 24 months, a significantly lower mean IOP was reported following trabeculectomy ($p<0.00001$, $p<0.00001$, $p<0.0001$, respectively). Trabeculectomy patients required a significantly less number of postoperative antiglaucomatous medications compared to viscocanalostomy ($P<0.00001$). Six studies reported that viscocanalostomy had a significantly higher relative risk of perforation of Descemet membrane ($p=0.007$). The relative risk of hypotony, hyphema, shallow anterior chamber, and cataract formation were significantly less in the viscocanalostomy group ($p=0.0005$, $p=0.008$, $p=0.0002$, $p=0.002$, respectively). Author-noted limitations of the study include: the studies may not be completely comparable due to various surgical techniques and surgeon experience; two studies lacked data on IOP; and the follow-ups were short-term.

Hondur et al. (2008) performed a meta-analysis of randomized controlled trials and case series that evaluated nonpenetrating glaucoma surgery (NPGS), including deep sclerectomy (n=22) and viscocanalostomy (n=14) for the treatment of OAG. Success was defined as IOP of ≤ 21 millimeters of mercury (mmHg) without the use of antiglaucoma medicine. Because they affect the results of NPGS, data related to postoperative goniopuncture and needling with antimetabolite application were noted. In general, the mean follow-up of the viscocanalostomy studies was 25.6 months. The percentage of cases achieving ≤ 21 mmHg was 51.1% following primary viscocanalostomy (n=9) and 36.8% after viscocanalostomy with antimetabolite or implant (n=3). With lower set IOP targets, the rates of success ranged from 10%–67% following viscocanalostomy. Several factors were identified that may account for the wide variation in the success rates of NPGS including the variations in surgical techniques (i.e., use of implants and antimetabolite application) and post-operative manipulation (e.g., goniopuncture, subconjunctival 5-FU injection), variations in success criteria and targeted IOPs, and differences in follow-up lengths. There was an absence of data regarding the severity of glaucoma in the pre-operative patient populations and a lack of data regarding visual acuity following viscocanalostomy. The authors noted that data regarding the success of NPGS beyond three years was limited. According to the authors, the analysis implied that NPGS can achieve IOP reduction. However, these procedures "may not be suitable surgical options for patients in whom vigorous IOP reduction is required." Long-term studies with data related to glaucoma severity and proper target IOPs are needed.

Earlier published reports from randomized controlled trials also compared the results of viscocanalostomy to trabeculectomy for the treatment of glaucoma (Gilmour, et al., 2007; Cheng, et al., 2004; O'Brart, et al., 2004; Yalvac, et al., 2004; Yarangümeli, et al., 2004; Carassa, et al., 2003; Kobayashi, et al., 2003; O'Brart, et al., 2002; Lüke, et al., 2002; Jonescu-Cuypers, et al., 2001). Overall, trabeculectomy provided a statistically significant decrease in IOP and an increase in IOP control compared to viscocanalostomy. Reported complications were varied and conflicting. Some studies reported no significant differences in complications while others reported a lower incidence of post-operative cataract formation and hypotony following viscocanalostomy.

Literature Review – Canaloplasty
There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of canaloplasty for the treatment of glaucoma. Studies are primarily in the form of case series with heterogeneous patient populations and short-term follow-ups. Comparisons of canaloplasty to established treatment modalities are lacking. Many questions remain regarding the proper degree of tension of the suture, long-term effect of the suture in the canal, and resultant microscopic changes in the outflow system morphology (Shingleton, et al., 2008).

Grieshaber et al. (2010) randomly selected 60 eyes from consecutive patients to evaluate the efficacy and safety of canaloplasty in patients with primary open-angle glaucoma. Mean follow-up was 30.6 ± 8.4 months. The mean preoperative IOP was 45.0 ± 2.1 mmHg compared to a mean postoperative IOP (without medications) at six months of 15.4 ± 5.4 mmHg (n=57), at 12 months 15.4 ± 5.2 mmHg (n=54), at 24 months 16.3 ± 4.2 mmHg (n=51), and at 36 months 13.3 ± 1.7 mmHg (n=49). For IOP ≤ 21 mmHg, complete success rate (without medications) was 77.5% (38/49), and qualified success rate (with or without medications) was 81.6% (40/49) at 36 months. The complete success rate of an IOP of 21, 18 or 16 mmHg or less after 36 months was 81%, 67.8% and 47.2%, respectively. During the three-year follow-up, best corrected visual acuity did not deteriorate in 57 eyes (95%). Complications included two detachments of Descemet's membrane, and one passage of the microcatheter into the anterior chamber and one in the suprachoroidal layer. Limitation of the study include the small patient population, short-term follow-up, lack of comparison to an established treatment option, and patients (n=11) lost to follow-up.

Lewis et al. (2009) reported on an ongoing 14-center, open-label study (n=127) conducted to demonstrate the safety and efficacy of canaloplasty. Diagnoses included primary OAG, pigmentary dispersion glaucoma, exfoliation glaucoma or primary OAG mixed with another type of glaucoma. Efficacy analysis of canaloplasty was based on three subgroups. Group 1 (n=127) included all patients, group 2 (n=97) included patients with successful suture implantation during canaloplasty alone, and group 3 (n=32) included patients with successful suture implantation during canaloplasty plus cataract surgery. At 24 months, all patients had a mean IOP of 16.0 mmHg ± 4.2 and a mean glaucoma medication use of 0.5 ± 0.8. Patients treated with canaloplasty alone had a mean IOP of 16.3 ± 3.7 mmHg and 0.6 ± 0.8 mean medications and eyes with combined surgery had a mean IOP of 13.4 ± 4.0 mmHg and 0.2 ± 0.4 mean medications. All results were statistically significant compared to the baseline values (P<0.001). The most frequent post-operative intervention was cataract surgery (8.6%) and laser goniopuncture (4.7%). Three patients had increased IOP at the 24-month follow-up and three patients lost 3 or more lines of best corrected visual acuity. The two most frequent post-operative complications (7.9% each) were microhyphema and early elevated IOP in the first three months (7.9% each). Other complications included: hyphema (6.3%), blebs (3.8%), and late elevated IOP (2.4%). In addition to the small heterogeneous patient population and short-term follow-ups, limitations of the study include lack of randomization, and comparison to an established surgical intervention. The authors noted that long-term results and comparative studies are needed to validate the results of this study.

In a prospective case series involving nine centers, Shingleton et al. (2008) evaluated the safety and efficacy of canaloplasty combined with clear corneal phacoemulsification and posterior chamber intraocular lens (IOL) implantation for the treatment of OAG. Adult patients (n=54 eyes) with qualifying treated preoperative IOP of at least 21 mmHg or higher and open angles were eligible. At the three-, six-, and 12-month follow-ups, 85%, 89%, and 74% of eyes were examined, respectively. In all eyes, the mean postoperative IOP was 13.6 ± 3.8 mmHg at 1 month, 14.2 ± 3.6 mmHg at 3 months, 13.0 ± 2.9 mmHg at 6 months, and 13.7 ± 4.4 mmHg at 12 months (p<0.0001). Medication use dropped to a mean of 0.2 ± 0.4 per patient at 12 months (p< 0.0001). Overall, a mean improvement in best corrected visual acuity was observed after 12 months. Surgical complications included hyphema (n=3, 5.6%), Descemet tear (n=1, 1.9%), and iris prolapse (n=1, 1.9%). Transient IOP elevation of more than 30 mmHg was observed in four eyes (7.3%) one day postoperatively. Author-noted limitations of the study included lack of randomization and a control group. It was also acknowledged that the learning curve inherent to this and many new surgical procedures also played a key role in outcomes, as sites with larger numbers of enrolled patients had greater success with the procedure.

Literature Review – Phacoviscocanalostomy
The evidence in the published peer-reviewed literature does not support the safety and efficacy of phacoviscocanalostomy for the treatment of glaucoma. Published studies include a limited number of case series and retrospective reviews with small patient populations and short-term follow-ups. The effects on postoperative medication usage, as well as the long-term effects of phacoviscocanalostomy are unknown. Studies comparing phacoviscocanalostomy to established treatment modalities are lacking.

Kobayashi and Kobayashi (2007) conducted a trial including 40 patients who had primary OAG unresponsive to medical management. One eye was randomized to undergo either phacotrabeculectomy with mitomycin C (n=20) or phacoviscocanalostomy with phacoemulsification and intraocular lens implantation (n=20). When both eyes were eligible, the right eye became the study eye. Following surgery, goniopuncture was performed in the phacoviscocanalostomy group if the IOP was not low enough and laser suture lysis was performed in the phacotrabeculectomy group if the bleb was flat or the IOP was not low enough. Mean baseline IOP in the phacoviscocanalostomy group was 24.0 ± 2.0 mmHg compared to a 12-month postoperative value of 14.9 ± 3.0 mmHg. In the phacotrabeculectomy group, mean baseline IOP was 23.7 ± 2.6 mmHg compared to 14.1 ± 4.4 mmHg, 12 months postoperatively. There were no significant differences in the IOP between the two groups at anytime during the one year follow-up, but the values were consistently lower in the phacotrabeculectomy group. At 12 months, an IOP of 20 mmHg or less was achieved by 17 viscocanalostomy patients and 16 trabeculectomy patients. Complications included intraoperative microperforation of Descemet's membrane in the viscocanalostomy group and flat/shallow anterior chamber and hypotony in the trabeculectomy group. Although better in the phacoviscocanalostomy group, the difference in the mean best corrected visual acuity between the two groups was not statistically significant. The authors noted that the small patient population was a limitation of the study that precluded assessment of safety and that a "masked study design might have reduced observer bias."

Wishart et al. (2006) prospectively evaluated the outcomes of 165 consecutive eyes treated with phacoviscocanalostomy in patients with cataracts and medically uncontrolled glaucoma. The mean follow-up was 38.7 months. One day postoperatively, the mean IOP dropped from 24.1 ± 5.1 mmHg to 13.8 ± 8.1 mmHg ($p<0.001$) which was persistent to the final follow-up. At the final follow-up, 48.5% of the eyes had achieved complete success (i.e., IOP reduction of ≥ 30% without medication). At five years, 80.6% of eyes had an IOP of 21 mmHg or less without the use of medication. Mean IOP was 16.6 ± 4.4 mmHg at the 72-month follow-up (n=17) compared to 13.8 ± 8.1 mmHg at one day postoperative. Medication usage dropped from a mean per eye of 2.5 ± 0.9 preoperatively to 0.1 ± 0.5 at last follow-up ($p<0.001$). Complications included zonular dehiscence with no vitreous loss, posterior capsule tear with vitreous loss, peripheral choroidal detachment not affecting the macula, a tear of the trabecular meshwork-Descemet's membrane (TDW) requiring peripheral iridotomy, and microperforation of the TDW with no iris prolapse. Loss of visual acuity in five patients was attributed to progressive glaucoma and preexisting age-related macular degeneration. No long-term bleb-related complications occurred.

Professional Societies/Organizations
American Academy of Ophthalmology (AAO): The AAO (2010) practice guidelines on the management of primary OAG described viscocanalostomy as a nonpenetrating surgery used by some physicians as an alternative to trabeculectomy, but they stated that the precise role of nonpenetrating surgeries (i.e., viscocanalostomy and nonpenetrating deep sclerectomy) is yet to be determined. They also noted that the role of canaloplasty is currently under evaluation.
National Institute for Health and Clinical Excellence (NICE): In their 2009 full guidance document on the diagnosis and management of chronic open-angle (OAG) and ocular hypertension, NICE (United Kingdom) concluded from the evidence (low to moderate quality) that trabeculectomy is more effective than non-penetrating surgery (e.g., viscocanalostomy) in reducing IOP from baseline at six- and 12-month follow-ups, but the effect size may be too small to be clinically significant. Trabeculectomy is also more effective in reducing the number of eyes with unacceptable IOP at six- and 12-month follow-ups. Regarding complications,

trabeculectomy is more likely to cause cataract formation and persistent hypotony compared to non-penetrating surgery, but there were no significant differences in postoperative wound leaks. Regarding canaloplasty, NICE (2008) stated that the procedure should be used only in the "context of research or formal prospective data collection" for the treatment of primary OAG. They noted that the current evidence on the safety and efficacy of canaloplasty is inadequate in quality and quantity.

Summary
Evidence in the published peer-reviewed scientific literature does not support the efficacy of viscocanalostomy for the treatment of glaucoma. The available data indicate that viscocanalostomy is not as effective as trabeculectomy, the standard surgical procedure, in reducing intraocular pressure in patients with glaucoma. Evidence supporting the safety and efficacy of canaloplasty or phacoviscocanalostomy for the treatment of glaucoma is lacking. The published studies include small heterogeneous patient populations with short-term follow-ups and lack of a comparison to established methods of treatment.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
0176T	Transluminal dilation of aqueous outflow canal; without retention of device or stent (Code deleted 12/31/2010)
0177T	Transluminal dilation of aqueous outflow canal; with retention of device or stent (Code deleted 12/31/2010)
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent (Code effective 01/01/2011)
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent (Code effective 01/01/2011)

ICD-9-CM Diagnosis Codes	Description
365.00-365.9	Glaucoma
	All other codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0035	Viscocanalostomy and Canaloplasty