MEDICAL POLICY

GLAUCOMA SURGICAL TREATMENTS

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.

Glaucoma Surgical Treatments: Medical Policy (Effective 06/01/2014)

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**COVERAGE RATIONALE**

Glaucoma drainage devices, such as the ExPRESS™ mini glaucoma shunt, Molteno implant, Baerveldt tube shunt, Krupin Eye Valve, or the Ahmed glaucoma valve implant, are proven and medically necessary for treatment of refractory glaucoma when there is intolerance, contraindication, or failure of topical or oral medication, when used according to U.S. Food and Drug Administration (FDA) labeled indications.

The iStent® Trabecular Micro-Bypass Stent System is proven and medically necessary when used in combination with cataract surgery to treat mild to moderate open-angle glaucoma and a cataract in adults currently being treated with ocular hypotensive medication.

Glaucoma drainage devices, such as Eyepass, DeepLight SOLX® Gold Shunt and other shunts that do not have FDA approval are investigational and unproven and not medically necessary for the treatment of glaucoma. Clinical evidence is limited to small studies; therefore, additional studies are needed to establish the safety and efficacy of these devices.

Canaloplasty is proven and medically necessary for the treatment of primary open-angle glaucoma.

Viscocanalostomy is unproven and not medically necessary for the treatment of glaucoma. Evidence from the majority of available randomized controlled trials indicates that viscocanalostomy is not as effective as trabeculectomy in reducing intraocular pressure (IOP).

Transciliary fistulization is unproven and not medically necessary for the treatment of glaucoma. Further studies are needed to evaluate long-term safety and efficacy in comparison to established filtering procedures. The currently available published data are insufficient to draw any conclusion regarding health outcomes of transciliary fistulization for the treatment of glaucoma.

**APPLICABLE CODES**

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
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<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>0123T</td>
<td>Fistulization of sclera for glaucoma, through ciliary body</td>
</tr>
<tr>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extracocular reservoir; internal approach, into the trabecular meshwork</td>
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<tr>
<td>0253T</td>
<td>Insertion of anterior segment aqueous drainage device, without extracocular reservoir; internal approach, into the suprachoroidal space</td>
</tr>
<tr>
<td>66174</td>
<td>Transluminal dilation of aqueous outflow canal; without retention of device or stent</td>
</tr>
<tr>
<td>66175</td>
<td>Transluminal dilation of aqueous outflow canal; with retention of device or stent</td>
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Glaucoma Surgical Treatments: Medical Policy (Effective 06/01/2014)

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<tr>
<th>CPT™ Code</th>
<th>Description</th>
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<tr>
<td>66180</td>
<td>Aqueous shunt to extraocular reservoir (e.g., Molteno, Schocket, Denver-Krupin)</td>
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<tr>
<td>66183</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach</td>
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**HCPCS Code**

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<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>L8612</td>
<td>Aqueous shunt</td>
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**DESCRIPTION OF SERVICES**

Glaucoma refers to a group of eye diseases in which vision is lost due to damage of the optic nerve. The 2010 American Academy of Ophthalmology (AAO) Preferred Practice Patterns Guidelines report on primary open-angle glaucoma states that the severity of glaucoma damage can be estimated using the following:

- **Mild:** optic nerve abnormalities consistent with glaucoma and a normal visual field as tested with standard automated perimetry
- **Moderate:** optic nerve abnormalities consistent with glaucoma and visual field abnormalities in one hemifield that are not within 5 degrees of fixation as tested with standard automated perimetry
- **Severe:** optic nerve abnormalities consistent with glaucoma as and visual field abnormalities in both hemifields and/or loss within 5 degrees of fixation in at least one hemifield as tested with standard automated perimetry

Glaucoma drainage devices include the ExPRESS Mini Glaucoma Shunt, the Molteno implant, the Baerveldt tube shunt, or the Ahmed glaucoma valve implant. The ExPRESS Mini Glaucoma Shunt is a small stainless steel device that is placed beneath the scleral flap into the anterior chamber instead of creating a punch or excisional sclerostomy, thereby bypassing the trabecular meshwork and directing aqueous fluid to form a perilimbal conjunctiva-covered bleb. The Molteno, Baerveldt and Ahmed glaucoma implants consist of a length of flexible plastic tubing that is inserted into anterior or posterior chamber and connect to a plastic or silicone plate with a large surface area that is secured to the posterior sclera between two of the extraocular muscles, and covered by conjunctiva. The plate acts as a physical barrier to scarring of the conjunctiva to the sclera providing a large surface area bleb posterior to the limbus.

Glaucoma drainage devices, such as iStent, Eyepass, or DeepLight SOLX® Gold Shunt (suprachoroidal shunt) divert aqueous fluid from the anterior chamber directly into Schlemm’s canal (Samuelson, 2008). These stenting/shunting procedures are similar to viscocanalostomy in that they lower IOP without the formation of a filtering bleb.

Transciliary fistulization, also known as transciliary filtration or Singh filtration, uses a thermocauterization device called the Fugo Blade to create a plasma-ablated pore or filter track from the sclera through the ciliary body to allow aqueous fluid to ooze into the subconjunctival lymphatics from the posterior chamber (behind the iris) of the eye.

Viscocanalostomy 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.

Canaloplasty is a surgical technique for glaucoma which aims to restore the natural drainage of fluid from the eye (NICE, 2008). Canaloplasty involves viscodilation of the Schlemm’s canal with an illuminated tipped microcatheter. The microcatheter is used to place an intracanalicular suture that cinches and stretches the trabecular meshwork inwards while permanently opening the
Schlemm’s canal.

The difference between a viscocanalostomy and a canaloplasty is that the canaloplasty aims at opening the entire length of the canal, not just one section of it. Canaloplasty and viscocanalostomy are referred to as nonpenetrating procedures.

Trabeculectomy is a surgical procedure that removes part of the eye's trabecular meshwork and adjacent structures to reduce intraocular pressure in patients with glaucoma. For the majority of patients it is the most common surgery that allows drainage of aqueous humor from within the eye to underneath the conjunctiva where it is absorbed.

CLINICAL EVIDENCE

Glaucoma Drainage Devices Approved by the U.S. Food and Drug Administration (FDA)

iStent: Arriola-Vilaobos et al. (2013) conducted a prospective, non-comparative, uncontrolled, Interventional case study to evaluate the mid-term efficacy and safety of the GTS-400- iStent combined with phacoemulsification in patients with cataract and open glaucoma (OAG or ocular hypertension. Prospective, non-comparative, uncontrolled, interventional case series study. Subjects underwent phacoemulsification and two GTS-400 implantation. Efficacy outcomes: intraocular pressure (IOP) and antiglaucoma medications. Safety outcomes: complications, best-corrected visual acuity and endothelial cell count (ECC). Follow-up was 1 year. 20 patients were enrolled (mean age: 75.1 ± 8.6 years). Mean medicated baseline IOP was 19.95 ± 3.71 mm Hg and 26 ± 3.11 mm Hg without medication. Mean final IOP was 16.75 ± 2.24, determining a final IOP decrease of 35.68% (9.42 ± 3 mm Hg; p<0.001), from baseline washout IOP. Mean number of medications fell from 1.3 ± 0.66 to 0.3 ± 0.57 (P<0.001). 75% of patients were off medications at one year. Mean ECC decreased from 2289.64 ± 393.5 cells/mm(2) to 1986.95 ± 520.58 cells/mm(2). Combined cataract surgery with implantation of GTS-400-iStent appeared to be an effective and safe service.

Craven et al. (2012) assessed the long-term safety and efficacy of a single trabecular micro-bypass stent with concomitant cataract surgery versus cataract surgery alone for mild to moderate open-angle glaucoma in a prospective randomized controlled multicenter clinical trial. Data was collected from 239 patients randomized to two groups: 116 patients underwent iStent placement during cataract surgery and 123 control patients had routine cataract surgery without iStent placement. Patients were followed for 24 months postoperatively with minimal dropout rate (three lost to follow-up in the treatment group and four in the control group). The incidence of adverse events was low in both groups through 24 months of follow-up. At 24 months, 61% of patients who underwent placement of the iStent during cataract surgery had an IOP less than 21 mm Hg without ocular hypotensive medications as compared to 50% of patients after cataract surgery alone. This difference was statistically significant. Cataract surgery alone resulted in a mean decrease in IOP of 7.5 mm Hg compared to 8.4 mm Hg in the iStent group. Overall, the mean IOP was stable between 12 months and 24 months in the stent group but increased in the control group. Ocular hypotensive medication was statistically significantly lower in the stent group at 12 months; it was also lower at 24 months, although the difference was no longer statistically significant. The authors concluded that patients with combined single trabecular micro-bypass stent and cataract surgery had significantly better IOP control on no medication through 24 months than patients having cataract surgery alone. Both groups had a similar favorable long-term safety profile.

Samuelson et al. (2011) assessed the safety and efficacy of the iStent trabecular micro-bypass stent (Glaukos Corporation, Laguna Hills, CA) in combination with cataract surgery in a prospective, randomized, open-label, controlled, multicenter clinical trial. A total of 240 eyes with mild to moderate open-angle glaucoma with intraocular pressure (IOP) ≤24 mmHg controlled on 1 to 3 medications were randomized to undergo cataract surgery with iStent implantation (treatment group) or cataract surgery only (control). Fifty additional patients were enrolled to undergo
cataract surgery with iStent implantation under protocol expansion. The primary efficacy measure was unmedicated IOP ≤21 mmHg at 1 year. The study met the primary outcome, with 72% of treatment eyes versus 50% of control eyes achieving the criterion. At 1 year, IOP in both treatment groups was statistically significantly lower from baseline values. Sixty-six percent of treatment eyes versus 48% of control eyes achieved 20% or more IOP reduction without medication. The overall incidence of adverse events was similar between groups with no unanticipated adverse device effects. The investigators concluded that pressure reduction on fewer medications was clinically and statistically significantly better 1 year after stent plus cataract surgery versus cataract surgery alone, with an overall safety profile similar to that of cataract surgery alone.

Fernandez-Barrientos et al. (2010) evaluated the changes in aqueous humor dynamics and the efficacy and safety of the iStent in combination with cataract surgery in a prospective, randomized, clinical study in patients with open-angle glaucoma or ocular hypertension who were undergoing cataract surgery. Thirty-three eyes of 33 patients were randomized to either two stents and cataract surgery (n = 17, group 1) or cataract surgery alone (n = 16, group 2). Before surgery, aqueous flow (F) and trabecular outflow facility (C(T)) were similar in groups 1 and 2. After surgery, there were no changes of note in F, however, C(T) increased in both groups. At 1 year, C(T) was 0.45 +/- 0.27 microL/min/mm Hg in group 1 and 0.19 +/- 0.05 microL/min/mm Hg in group 2, which represented increases of 275% and 46%, respectively. Mean IOP reduction was also greater in group 1 than in group 2. The mean number of medications was significantly lower in group 1 than in group 2. The investigators concluded that compared with cataract surgery alone, implantation of the iStent concomitant with cataract extraction significantly increased trabecular outflow facility, reduced IOP, and reduced the number of medications at 1 year.

Fea (2010) compared phacoemulsification alone and phacoemulsification with micro-bypass stent implantation in 36 patients with primary open-angle glaucoma in a prospective double-masked randomized clinical trial. The study included patients who had phacoemulsification alone (control group) or phacoemulsification with iStent implantation (combined group). Primary outcomes were intraocular pressure (IOP) and reduction in medication use over 15 months and IOP after a 1-month washout of ocular hypotensive agents (i.e., 16 months postoperatively). The baseline IOP was similar between groups. Three patients in the control group were lost to follow-up. The mean IOP was 14.8 mm Hg in the combined group and 15.7 mm Hg in the control group at 15 months and 16.6 mm Hg and 19.2 mm Hg, respectively, after washout; the IOP was statistically significantly lower in the combined group than in the control group at both time points. At 15 months, the mean number of medications was lower in the combined group than in the control group, as was the proportion of patients on ocular hypotensive medication. The investigators concluded that phacoemulsification with stent implantation was more effective in controlling IOP than phacoemulsification alone; the safety profiles were similar.

Arriola-Villalobos et al. (2012) evaluated the long-term efficacy and safety of combined cataract surgery and Glaukos iStent implantation for coexistent open-angle glaucoma and cataract. This prospective case series included 19 patients. Mean follow-up was 53.68 months. Mean intraocular pressure (IOP) was reduced from 19.42 mm Hg at the end of follow up, indicating a 16.33% to 16.26 mm decrease in IOP. The mean number of pressure-lowering medications used by the patients fell from 1.32 to 0.84. In 42% of patients, no antiglaucoma medications were used at the end of follow-up. Mean best-corrected visual acuity significantly improved from 0.29 to 0.62. The authors concluded that combined cataract surgery and Glaukos iStent implantation seems to be an effective and safe procedure to treat coexistent open-angle glaucoma and cataract.

In a prospective case series, Belovay et al. (2012) evaluated the efficacy and safety of multiple trabecular micro-bypass stents in 47 cataract patients (mean age 77.2 years) (53 eyes) to treat primary open-angle glaucoma (POAG). Either 2 (n=26) or 3 (n=23) stents were implanted along
with concurrent cataract surgery. Efficacy measures were IOP and topical ocular hypotensive medication use. Patients were followed for 1 year. The overall mean 1-year postoperative IOP was 14.3 mm Hg, which was significantly lower than preoperative IOP overall and in each group. The target IOP was achieved in a significantly higher proportion of eyes at 1 year versus preoperatively (77% versus 43%). Overall, 83% of eyes had a decrease in topical ocular hypotensive medication at 1 year from preoperatively, with a 74% decrease in the mean number of medications (from 2.7 to 0.7) at 1 year. The 3-stent group was on significantly fewer medications than the 2-stent group at 1 year. The authors concluded that the use of multiple micro-bypass stents with concurrent cataract surgery led to a mean postoperative IOP of less than 15 mm Hg and allowed patients to achieve target pressure control with significantly fewer medications through 1 year.

Buchacra et al. (2011) evaluated the midterm efficacy and safety of the iStent glaucoma device in a prospective, nonrandomized, interventional case series involving 10 patients with secondary open-angle glaucoma (traumatic, steroid, pseudoexfoliative, and pigmentary glaucoma). Patients were assessed following the procedure on days 1, 7, and 15 and months 1, 3, 6, and 12. The mean baseline IOP was 26.5 ± 7.9 (range 18-40) mmHg, and significantly decreased in 10.4 ± 9.2 mmHg at three months, in 7.4 ± 4.9 mmHg at six months, and in 6.6 ± 5.4 mmHg at 12 months following iStent implantation. The mean number of hypotensive medications at baseline was 2.9 ± 0.7 (range 2-4). Statistically significant reductions in the number of medications of 1.1 ± 1.1 were observed at three months, 1.0 ± 0.7 at six months, and 1.1 ± 0.6 at 12 months. No significant changes in visual acuity were noted. The most common complications comprised mild hyphema in seven eyes and transient IOP ≥30 mmHg in three eyes on postoperative day 1. Obstruction of the lumen of the stent with a blood clot was seen in three eyes, and all instances resolved spontaneously. According to the authors, this study shows that iStent implantation without concomitant cataract surgery is a safe treatment option in patients with secondary open-angle glaucoma.

In 2009, Spiegel et al. reported the interim results of a prospective, 24-month, uncontrolled, multicenter, multi-country evaluation of patients undergoing concurrent cataract and glaucoma surgery with the iStent Trabecular Micro-bypass Stent. The interim analysis included 42 patients of the 48 per protocol population who completed 12 months of the 24-month study. At 12 months, mean IOP was reduced from 21.7+/-3.98 mmHg at baseline to 17.4+/-2.99 mmHg, a mean IOP reduction of 4.4+/-.454 mmHg. At baseline, patients were taking a mean 1.6+/-.8 medications. By 12 months, the mean number of medications was reduced to 0.4+/-.62. Half the patients achieved an IOP < or =18 mmHg and were able to discontinue hypotensive medication by the 12-month visit. The most commonly reported device-related adverse events were the appearance of stent lumen obstruction (7 eyes) and stent malposition (6 eyes). None of the adverse events were deemed serious.

A National Institute for Health and Clinical Excellence (NICE) interventional procedure guidance for Trabecular Stent Bypass Microsurgery for Open Angle Glaucoma states that current evidence on trabecular stent bypass microsurgery for open angle glaucoma raises no major safety concerns. There is evidence of efficacy in the short term but this is based on small numbers of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE 2011).

A 2013 Hayes Report for the iStent Trabecular Micro-Bypass Stent indicates that overall, the quality of the evidence is low since the available randomized controlled trials (RCTs) have inadequate follow-up, and the remaining studies lack controls. The best available evidence of efficacy was obtained in an RCT with 2 years of follow-up (Craven et al. 2012), which found that in comparison with cataract surgery alone, iStent implantation was associated with statistically significant reductions in IOP and mean medication use with only a few, mild intraoperative and postoperative complications. All studies reported significant reductions in IOP compared with cataract surgery alone, as well as significant decreases in use of ocular medications. In some
patients, medications were discontinued entirely. Furthermore, visual acuity improved in the majority of patients.

Several registered ongoing clinical trials relevant to the iStent were identified on ClinicalTrials.gov. See the following Web site for more information: http://www.clinicaltrials.gov/ct2/results?term=iStent March 17, 2014

**Ex-PRESS:**

De Jong (2009) conducted a prospective, randomized trial of 78 patients (80 eyes) with primary open-angle, pseudoexfoliative, or pigmentary glaucoma to compare the Ex-PRESS mini glaucoma shunt with trabeculectomy. A total of 84.6% of patients receiving Ex-PRESS and 60.0% of patients receiving trabeculectomy achieved complete success. Complete success was defined as an IOP of >4 mmHg \( \leq \)18 mmHg without the use of antiglaucoma medications. The respective proportions of patients achieving an intraocular pressure (IOP) >4 mmHg and \( \leq \)15 mmHg were 76.9% and 50.0%. At 1-year follow-up, complete success rates were 81.8% for Ex-PRESS and 47.5% for trabeculectomy, and 71.7% and 37.5%, respectively, for the more stringent target. The authors concluded that the Ex-PRESS mini glaucoma shunt implanted under a superficial scleral flap produces significantly higher success rates compared with trabeculectomy.

De Jong et al. (2011) reported on outcomes at 4 years beyond those in the original randomized controlled trial by de Jong (2009), i.e., up to 5 years in the 78 patients who received either the Ex-PRESS device (n=39) or who underwent a trabeculectomy (n=39). Compared with trabeculectomy, the Ex-PRESS device controlled IOP more effectively without medication in a higher percentage of patients from year 1 (66.8% versus 61.5%) to year 3 (66.7% versus 41.0%) after treatment. At 1 year posttreatment, only 12.8% of patients required IOP medication after Ex-PRESS implantation, compared with 35.9% after trabeculectomy; however, the proportions became closer each year and at 5 years were 41% versus 53.9%, respectively. Up to the end of the third year after surgery, IOP remained better controlled by Ex-PRESS devices than by trabeculectomy. In the fourth and fifth years, the differences in IOP control between the two groups were not significant.

Ates et al. (2010) evaluated intraocular pressure (IOP) control and graft survival after Ex-PRESS mini glaucoma shunt implantation in 15 patients. IOP decreased from 41.46 mm Hg to 12.06 mm Hg over a mean follow-up of 12.2 months. Neither biomicroscopy nor pachymetry showed worsening of preoperatively opaque grafts. The investigators concluded that the Ex-PRESS mini glaucoma shunt implantation may be an effective procedure for refractory post-penetrating keratoplasty glaucoma with acceptable graft failure rates in short term.

**Molteno Implant, Baerveldt Tube Shunt and Ahmed Glaucoma Valve Implant:**

A Cochrane review compared various aqueous shunts for intraocular pressure (IOP) control and safety (Minkler, 2006). Only randomized and quasi-randomized trials were included. This included 15 trials with a total of 1153 participants with mixed diagnoses. Five studies reported details sufficient to verify the method of randomization but only two had adequate allocation concealment. Data collection and follow-up times were variable. Meta-analysis of two trials comparing Ahmed implant with trabeculectomy found trabeculectomy resulted in lower mean IOPs 11 to 13 months later. One study concluded there were outcome advantages with a double versus a single-plate Molteno implant and one trial comparing the 350 mm2 and 500 mm2 Baerveldt shunts found no clinically significant advantage of the larger device but neither of these trials included all patients randomized. One study comparing endocyclophotocoagulation (ECP) with Ahmed implant in complicated glaucomas found no evidence of better IOP control with Ahmed implant over ECP. The authors concluded that there are relatively few randomized trials that have been published on aqueous shunts, therefore methodology and data quality among them is poor. To date there is no evidence of superiority of one shunt over another. This meta-
analysis was a review of comparative studies and did not evaluated whether aqueous shunts could lower intraocular pressure.

Budenz et al. (2011) evaluated the relative efficacy and complications of the Ahmed glaucoma valve (AGV) (New World Medical, Ranchos Cucamonga, CA) and the Baerveldt glaucoma implant (BGI) (Abbott Medical Optics, Abbott Park, IL) in refractory glaucoma in a multicenter, randomized, controlled clinical trial. The study included 276 patients (143 in the AGV group and 133 in the BGI group). Preoperative IOP was 31.2±11.2 mmHg in the AGV group and 31.8±12.5 mmHg in the BGI group. At 1 year, mean±SD IOP was 15.4±5.5 mmHg in the AGV group and 13.2±6.8 mmHg in the BGI group. The mean±SD number of glaucoma medications was 1.8±1.3 in the AGV group and 1.5±1.4 in the BGI group. The cumulative probability of failure was 16.4% in the AGV group and 14.0% in the BGI group at 1 year. More patients experienced early postoperative complications in the BGI group (n = 77; 58%) compared with the AGV group (n = 61; 43%). Serious postoperative complications associated with reoperation, vision loss of ≥2 Snellen lines, or both occurred in 29 patients (20%) in the AGV group and in 45 patients (34%) in the BGI group. The investigators concluded that although the average IOP after 1 year was slightly higher in patients who received an AGV, there were fewer early and serious postoperative complications associated with the use of the AGV than the BGI.

Gedde et al. (2009) evaluated the use of the Baerveldt glaucoma implant or trabeculectomy with mitomycin C in a multicenter randomized clinical trial (Tube versus Trabeculectomy (TVT) Study). A total of 212 eyes of 212 patients with uncontrolled glaucoma were enrolled, including 107 in the tube group and 105 in the trabeculectomy group. At 3 years, IOP was 13.0 mm Hg in the tube group and 13.3 mm Hg in the trabeculectomy group. The number of glaucoma medications was 1.3 in the tube group and 1.0 in the trabeculectomy group. The cumulative probability of failure during the first 3 years of follow-up was 15.1% in the tube group and 30.7% in the trabeculectomy group. Postoperative complications developed in 42 patients (39%) in the tube group and 63 patients (60%) in the trabeculectomy group. The investigators concluded that tube shunt surgery had a higher success rate compared to trabeculectomy during the first 3 years of follow-up in the TVT Study. Both procedures were associated with similar IOP reduction and use of supplemental medical therapy at 3 years. While the incidence of postoperative complications was higher following trabeculectomy with MMC relative to tube shunt surgery, most complications were transient and self-limited.

**Glaucoma Drainage Devices Not Approved by the U.S. Food and Drug Administration (FDA)**

*Eyepass*: Dietlein et al. (2008) conducted a small study to evaluate the safety and pressure-reducing efficacy of the Y-shaped Eyepass glaucoma implant in 12 glaucoma and cataract patients and found that combined cataract surgery with Eyepass shunt implantation was safe and appeared to be beneficial in glaucomatous eyes with cataract not requiring a low target IOP. Perforation of the trabecular meshwork during Eyepass implantation occurred in 2 eyes requiring explantation. In the remaining 10 eyes, the mean maximum IOP was 30.4 mm Hg preoperatively, 12.0 mm 1 day postoperatively, 17.2 mm Hg at 4 weeks, and 18.3 mm at the end of the preliminary follow-up.


According to an Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review evaluating treatment for glaucoma, the data available on the role of aqueous drainage devices in open-angle glaucoma are inadequate to draw conclusions about this treatment (Boland et al. 2012).

**Transciliary Fistulization**

Glaucoma Surgical Treatments: Medical Policy (Effective 06/01/2014)

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No studies that provide substantial new evidence regarding transciliary fistulization were identified in a January 2013 literature search.

Singh and Singh (2002) performed a case series with six months follow-up of 147 glaucoma patients treated with transciliary fistulization. At six months, the intraocular pressure (IOP) was reduced to 21 mm Hg or below without medication in 132 eyes. The decrease in IOP was statistically significant and no cases of anterior chamber flattening occurred. Adverse events included the need for surgical revision in seven patients three months after surgery, and choroidal effusion in two patients that resolved within one month after surgery. No data on changes in vision or optic neuropathy were reported. The value of this study is limited by short-term follow-up.

**Viscocanalostomy**

No studies that provide substantial new evidence regarding viscocanalostomy were identified in a January 2013 literature search.

Chai et al. (2010) conducted a meta-analysis to compare the efficacy and safety profile of viscocanalostomy versus trabeculectomy. Ten randomized controlled trials were selected and included in the meta-analysis with a total of 458 eyes of 397 patients with medically uncontrolled glaucoma. Trabeculectomy was found to have a significantly better pressure-lowering outcome. Viscocanalostomy had a significantly higher relative risk of intraoperative perforation of the Descemet membrane, whereas trabeculectomy had significantly more postoperative adverse events. The reviewers concluded that trabeculectomy had a greater pressure-lowering effect compared with viscocanalostomy. However, viscocanalostomy had a significantly better risk profile.

A meta-analysis by Hondur et al. (2008) evaluated the efficacy of nonpenetrating glaucoma surgery for open angle glaucoma with respect to target intraocular pressure (IOP) and severity of glaucoma. The studies reviewed included deep sclerectomy (DS) and viscocanalostomy (VC). The percentage of cases achieving \(<21\) mm Hg was 48.6% after primary DS, 68.7% after DS with implant, 67.1% after DS with antimetabolite, 51.1% after primary VC, and 36.8% after VC with antimetabolite or implant. Visual field parameters were almost exclusively not available; whereas cup/disk ratio and target IOP lower than 21 mm Hg were available in very few reports. With lower set IOP targets, the rates of success varied between 35% and 86% for DS, and between 10% and 67% for VC. Mean follow-up was mostly in the range of 3 years. The authors concluded that nonpenetrating glaucoma surgery seems to provide IOP reduction into the high teens. Its potential to achieve lower target IOPs seems to be low. Longer-term studies, with data related to glaucoma severity and proper target IOPs are required.

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.

Cheng et al. (2011) evaluated the intraocular pressure (IOP)-lowering effects achieved by nonpenetrating glaucoma surgery (NPGS) in patients with open angle glaucoma in a systematic review of randomized controlled trials. The pooled estimates were calculated using the random effects model. Both deep sclerectomy (DS) and viscocanalostomy (VCO) were less effective than trabeculectomy (TE) in lowering IOP, with the percentage IOP reductions at 2 years being 35.2% for DS, 30.2% for VCO, and 45.6% for TE. The complete success rates at 4 years were 35.4% for DS, and 22.7% for VCO, lower than that of TE (47.6%). According to the authors, primary deep sclerectomy and primary viscocanalostomy, which can significantly lower IOP, were associated with fewer complications than was TE. However, the IOP-lowering effects of both nonpenetrating glaucoma surgeries seem to be lower than that of primary TE.
Kobayashi (2007) compared the intraocular pressure (IOP) lowering effect of combined viscocanalostomy and phacoemulsification and combined trabeculectomy and phacoemulsification with mitomycin C in eyes with primary open-angle glaucoma. The prospective randomized 1-year trial included 40 consecutive patients (40 eyes) with primary open-angle glaucoma and cataract. Eyes were assigned randomly either to trabeculectomy with mitomycin C or to viscocanalostomy in combination with phacoemulsification and intraocular lens implantation. There was no significant difference in the mean IOP between the groups at any time. At 12 months, 17 patients (85%) in the viscocanalostomy group and 16 patients (80%) in the trabeculectomy group achieved an IOP of 20 mmHg or less without medication. Complications included 2 cases (10%) of flat/shallow anterior chamber and 4 cases (20%) of hypotony in the trabeculectomy group, whereas intraoperative microperforation of Descemet’s membrane occurred in 3 cases (15%) in the viscocanalostomy group. The investigators concluded that there was no significant difference in IOP reduction between viscocanalostomy and trabeculectomy with mitomycin C in combination with phacoemulsification and intraocular lens implantation in patients with primary open-angle glaucoma.

A randomized controlled trial by O’Bart et al. (2004) included 45 patients (50 eyes) with uncontrolled open angle glaucoma who were randomized to undergo trabeculectomy (25 eyes) or viscocanalostomy (25 eyes). At a mean follow-up of 20 months, complete success (IOP less than 21 mm Hg without medication) was seen in 68% of eyes in the trabeculectomy group and in 34% of eyes in the viscocanalostomy group. Viscocanalostomy was associated with less early transient postoperative complications.

Gilmour et al. (2009) conducted a study that included patients with glaucoma who were randomized to have a viscocanalostomy (25 eyes) or a trabeculectomy (25 eyes). Mean follow-up was 40 months. Forty-two percent (n=10) of the patients in the trabeculectomy group had a successful outcome (IOP<18 mm Hg with no treatment) at last follow-up visit, compared to 21% (n=5) in the viscocanalostomy group. IOP was lower in the trabeculectomy group.

Yalvac et al. (2004) evaluated 50 eyes of 50 patients with primary open-angle glaucoma who were randomized to undergo traneculectomy (25 eyes) or viscocanalostomy (25 eyes). Complete success (IOP 6-21 mm Hg without medication) was achieved in 55% of eyes in the trabeculectomy group and in 35% of eyes in the viscocanalostomy group at 3 years. Early transient complications occurred more frequently in the trabeculectomy group.

Koerber et al. (2012) compared the safety and efficacy of canaloplasty in one eye with viscocanalostomy in the contralateral eye in 15 patients (30 eyes) with bilateral primary open-angle glaucoma (POAG). Sixty percent of patients had the canaloplasty procedure first, followed by the viscocanalostomy procedure. At 18-month follow-up, both canaloplasty and viscocanalostomy were successful in reducing IOP. The percentage reduction in IOP was significantly higher in the canaloplasty eyes (approximately 44%), as compared with the viscocanalostomy eyes (approximately 33%), at both 12 and 18 months. Final absolute IOP was not significantly different, although lower, in the canaloplasty group versus the viscocanalostomy group at 18 months. Using the criteria for complete success defined as an IOP of ≤ 18 mm Hg without antiglaucoma medication, and qualified success as an IOP of ≤ 18 mm Hg with 1 or 2 antiglaucoma medications, the canaloplasty cohort achieved complete success in 60.0% of eyes, and complete or qualified success in 86.7% of eyes; the viscocanalostomy group achieved complete success in 35.7% of eyes, and complete or qualified success in 50.0% of eyes. On average, there was no loss of visual acuity from either procedure at 18 months as compared with baseline values. Complications were minimal in both groups. According to the authors, canaloplasty and viscocanalostomy were safe and effective in the surgical management of open-angle glaucoma. The authors also stated that canaloplasty procedures showed superior efficacy to viscocanalostomy in the reduction of IOP.
Yarangumeli et al. (2004) studied 44 eyes in 22 patients with glaucoma. One eye was randomly selected for trabeculectomy or viscocanalostomy, and the other eye was treated with the other surgical procedure 2 weeks later. At a mean follow-up of 18 months, complete success rates (IOP less than or equal to 18 mm Hg without medication) were 64% for trabeculectomy and 59% for the viscocanalostomy. Complication rates were similar between the 2 groups.

Earlier studies of viscocanalostomy indicate that this treatment is not as effective as trabeculectomy in reducing IOP (Luke, 2002; Jonescu-Cuypers, 2001; O'Brart, 2002; Carassa, 2003; Kobayashi, 2003). Four of the studies (Luke, 2002; Jonescu-Cuypers, 2001; O'Brart, 2002; Kobayashi, 2003) found that trabeculectomy provided statistically significant improvements in intraocular pressure (IOP) control relative to viscocanalostomy and the sole study (Carassa, 2003) that reported comparable efficacy for these two procedures had a methodological flaw that may have caused overestimation of the efficacy of viscocanalostomy. Although three of the studies found that viscocanalostomy was associated with a statistically significant decrease in the likelihood of certain complications, most of these complications were transient and/or minor (Luke, 2002; O'Brart, 2002; Kobayashi, 2003).

Evidence from the majority of available randomized controlled trials indicates that viscocanalostomy is not as effective as trabeculectomy or canaloplasty in reducing intraocular pressure (IOP) in patients with glaucoma. In these studies, viscocanalostomy was associated with a lower incidence of complications than was standard trabeculectomy. However, the complications reported with trabeculectomy were generally transient and relatively minor, and it remains to be proven whether the lower frequency of complications associated with viscocanalostomy outweighs its lower efficacy relative to trabeculectomy with regard to control of IOP.

In a guidance on the diagnosis and management of chronic open-angle (OAG) and ocular hypertension, the National Institute for Health and Clinical Excellence (NICE) 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 (NICE 2009).

Canaloplasty
Grieshaber et al. (2010) compared the safety and efficacy of two polypropylene (Prolene) sutures for tensioning of the inner wall of Schlemm's canal (SC) in patients with primary open-angle glaucoma (POAG) undergoing canaloplasty. This prospective randomized trial included 90 patients. After complete circumferential dilatation of the SC, a Prolene suture, either 6-0 Prolene (group 1) or 10-0 Prolene (group 2), was retracted through the SC and tightened leaving tension on the canal and trabecular meshwork. The mean preoperative intraocular pressure (IOP) was 42.7 mm Hg in group 1 and 45.0 mm Hg in group 2. The mean postoperative IOP without medications was 18.4 mm Hg in group 1 and 16.4 mm Hg in group 2 at 1 month, and 19.2 mm Hg in group 1 and 16.4 mm Hg in group 2 at 15 months. Pressures equal or less than 21, 18, and 16 mm Hg without medications (complete success) at 12 months were 51.0%, 34.1%, and 21.2% in group 1, and 76.9%, 68.8%, and 53.6% in group 2, respectively. The investigators concluded that IOP reduction was substantial in canaloplasty. Younger age, but not the level of IOP at surgery, had a positive effect on the amount of IOP reduction, thus suggesting that an early surgical intervention to re-establish physiological outflow offers the best prognosis.

Grieshaber et al. (2010a) evaluated the safety and effectiveness of 360° visco-dilation and tensioning of Schlemm canal (canaloplasty) in patients with primary open-angle glaucoma (POAG). Sixty randomly selected eyes of 60 consecutive patients with POAG were included in this prospective study. The mean preoperative intraocular pressure (IOP) was 45.0 mm Hg. The mean follow-up time was 30.6 months. The mean IOP at 12 months was 15.4 mm Hg (n=54), at
24 months 16.3 mm Hg (n = 51) and at 36 months 13.3 mm Hg (n=49). For IOP ≤ 21 mm Hg, complete success rate was 77.5% and qualified success rate was 81.6% at 36 months. Complication rate was low (Descemet's detachment n=2, elevated IOP n = 1, false passage of the catheter n = 2). The investigators conclude that canaloplasty produced a sustained long-term reduction of IOP in patients with POAG independent of preoperative IOP. As a bleb-independent procedure, canaloplasty may be a true alternative to classic filtering surgery, in particular in patients with enhanced wound healing and scar formation.

Lewis et al. (2011) conducted a multicenter clinical trial that included 157 eyes in 157 patients (140 patients with POAG, 17 patients with other glaucoma diagnoses) who underwent canaloplasty or combined cataract-canaloplasty surgery. A total of 121 eyes (77.1%) had canaloplasty alone, while 36 eyes (22.9%) with visually significant cataracts had canaloplasty combined with cataract extraction (phacocanaloplasty). Complete success (defined as attaining an IOP of ≤ 18 mm Hg without antiglaucoma medication) at 3-year follow-up was achieved in 36% of eyes receiving canaloplasty alone with successful suture placement, and 70.4% of eyes having the combined phacocanaloplasty procedure with successful suture placement. Complete or qualified success (defined as attaining an IOP of ≤ 18 mm Hg with 1 or 2 antiglaucoma medications) was achieved in 77.5% of eyes with canaloplasty alone, and 88.9% of eyes with phacocanaloplasty. The authors concluded that canaloplasty led to a significant and sustained IOP reduction in adult patients with open-angle glaucoma and had an excellent short- and long-term postoperative safety profile.

Bull et al. (2011) reported 3-year results investigating the safety and efficacy of canaloplasty in a prospective, multi-center, interventional study of 109 eyes of 109 adult, open-angle glaucoma patients undergoing canaloplasty or combined cataract-canaloplasty surgery. Intraocular pressure and medication use results for all study eyes were significantly decreased from baseline. According to the authors, canaloplasty demonstrated significant and sustained IOP reductions accompanied by an excellent short- and long-term safety profile in adult patients with open-angle glaucoma.

Findings reported in earlier prospective studies also indicate that canaloplasty may be a safe and effective procedure to reduce IOP in adult patients with open-angle glaucoma (Shingleton et al., 2008; Lewis et al., 2007; Lewis et al., 2009; Kearney et al., 2006).

A 2008 guideline from the National Institute for Health and Clinical Excellence (NICE) states that the current evidence on the safety and efficacy of canaloplasty for primary open-angle glaucoma is inadequate in both quality and quantity and this procedure should only be used in the context of research or formal prospective data collection.

According to an Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review evaluating treatment for glaucoma, trabeculectomy lowers IOP more than nonpenetrating surgeries. The authors also state that based on a systematic review, trabeculectomy results in more complications than nonpenetrating surgeries (Boland et al. 2012).

**Professional Societies**

**American Academy of Ophthalmology (AAO)**

The AAO Preferred Practice Patterns Committee and Glaucoma Panel (2010) considered viscocanalostomy and canaloplasty in their report on primary open-angle glaucoma. The following statement was made regarding these alternatives to current glaucoma: Nonpenetrating glaucoma surgery is an alternative to trabeculectomy. The precise role of nonpenetrating surgery in the surgical management of glaucoma remains to be determined. The two main types of nonpenetrating glaucoma surgery are viscocanalostomy and nonpenetrating deep sclerectomy. The rationale for nonpenetrating glaucoma surgery is that by avoiding a continuous passageway from the anterior chamber to the subconjunctival space, the incidence of complications such as bleb-related problems and hypotony can be reduced. The nonpenetrating procedures have a
higher degree of surgical difficulty compared with trabeculectomy and require special instrumentation. Randomized clinical trials comparing viscocanalostomy with trabeculectomy generally suggest greater IOP reduction with trabeculectomy, but more complications with viscocanalostomy. According to the AAO, other glaucoma surgical procedures currently under evaluation are cananoplasty with a tensioning suture (AAO 2010).

The 2010 AAO Preferred Practice Patterns Guidelines report on primary open-angle glaucoma states that other types of glaucoma surgery can also be combined with cataract surgery, such as implantation of glaucoma drainage devices. Combined cataract and glaucoma drainage device surgery can also improve vision while providing IOP control. Theses guidelines also state that the Ex-PRESS mini shunt for treatment of primary open-angle glaucoma is a surgical procedure that is currently under evaluation (AAO 2010).

In an Ophthalmic Technology Assessment, the AAO provided an evidence-based summary of commercially available aqueous shunts currently used in substantial numbers (Ahmed, Baerveldt, Krupin, and Moltene) that are used to control intraocular pressure (IOP) in various glaucomas. Seventeen previously published randomized trials, 1 prospective nonrandomized comparative trial, 1 retrospective case-control study, 2 comprehensive literature reviews, and published English language, non-comparative case series and case reports were reviewed and graded for methodologic quality. Aqueous shunts are used primarily after failure of medical, laser, and conventional filtering surgery to treat glaucoma and have been successful in controlling IOP in a variety of glaucomas. Although the primary indication for aqueous shunts is when prior medical or surgical therapy has failed, they may be used as primary surgical therapy for selected conditions such as trauma, chemical burns, or pemphigoid (level III evidence - case series, case reports, and poor quality cohort and case-control studies). The principal long-term complication of anterior chamber tubes is corneal endothelial failure. The most shunt-specific delayed complication is erosion of the tube through overlying conjunctiva. There is a low incidence of this occurring with all shunts currently available. Erosion of the equatorial plate through the conjunctival surface occurs less frequently. Clinical failure of the various devices over time occurs at a rate of approximately 10% per year, which is approximately the same as the failure rate for trabeculectomy. Based on level I evidence, aqueous shunts seem to have benefits (IOP control, duration of benefit) comparable with those of trabeculectomy in the management of complex glaucomas (phakic or pseudophakic eyes after prior failed trabeculectomies). Level I evidence indicates that there are no advantages to the adjunctive use of anti-fibrotic agents or systemic corticosteroids with currently available shunts. Too few high-quality direct comparisons of various available shunts have been published to assess the relative efficacy or complication rates of specific devices beyond the implication that larger-surface-area explants provide more enduring and better IOP control. Long-term follow-up and comparative studies are encouraged (Minckler, 2008).

An AAO technology assessment on novel glaucoma procedures (Francis et al, 2011) provided an evidence-based summary of clinically relevant information on novel devices for treating open-angle glaucoma (e.g., iStent, Ex-PRESS™ mini glaucoma shunt, SOLX® Gold Shunt). The report states that it is not possible to conclude whether these novel procedures are superior, equal to, or inferior to surgery such as trabeculectomy or to one another.

Canadian Ophthalmological Society
The Canadian Ophthalmological Society guidelines for the management of glaucoma in the adult eye lists viscocanalostomy under other strategies for the surgical management of coexisting cataract and glaucoma, but the guideline developers report that there is insufficient scientific evidence comparing these procedures to phaco-trabeculectomy (Canadian Ophthalmological Society, 2009).


The premarket approval application (PMA) for the iStent Trabecular Micro-Bypass Stent System, Model GTS100R/L, was approved by the FDA on June 25, 2012. This device is approved for use in combination with cataract surgery to reduce pressure inside the eye (intraocular pressure) in adult patients with mild to moderate open-angle glaucoma and a cataract who are currently being treated with medication to reduce intraocular pressure. Continued approval of the PMA is contingent upon the manufacturer submitting periodic reports to the FDA to provide reasonable assurance of the safety and effectiveness of the device.

Additional information is available at:
- http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm309667.htm
- http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm312053.htm

Viscocanalostomy and Canaloplasty: Specialized devices used for viscocanalostomy and canaloplasty are regulated by the FDA as Class II devices. Additional information may be obtained at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm under product codes HMX (cannula, ophthalmic), MPA (endoilluminator), or MRH (pump, infusion, ophthalmic). Accessed March 17, 2014.

The Canaloplasty Ophthalmic Microcannula, or iTRACK, is a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye such as the anterior chamber and posterior segment, for infusion and aspiration of fluids during surgery, including saline and viscoelastics. The FDA approved the Ophthalmic Microcannula in June 2004. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf4/k041108.pdf. Accessed March 17, 2014.

Viscocanalostomy and Canaloplasty: Specialized devices used for viscocanalostomy and canaloplasty are regulated by the FDA as Class II devices. Additional information may be obtained at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm under product codes HMX (cannula, ophthalmic), MPA (endoilluminator), or MRH (pump, infusion, ophthalmic). Accessed March 17, 2014.

The iScience Surgical Fiberoptic Illuminator provides localization of the Schlemm's canal and was approved by the FDA in August 2006. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062259.pdf. Accessed March 17, 2014.

Medicare does not have a National Coverage Determination (NCD) for surgical treatments for glaucoma (e.g., glaucoma drainage devices, transciliary fistulization, viscocanalostomy or canaloplasty). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for glaucoma drainage devices. Local Coverage Determinations (LCDs) exist for Glaucoma Treatment with Aqueous Drainage Device; also see the LCD for Non Covered Services and Category III Codes. Local Articles exist for Insertion of Anterior Segment Aqueous Drainage Device, without extraocular reservoir, external approach (0192T). Educational Article - Insertion of Anterior Segment Aqueous Drainage Device, without extraocular reservoir and 0192T: Aqueous Drainage Device for the Treatment of Glaucoma. (Accessed March 18, 2014)

REFERENCES


Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma. 2012 Feb;21(2):129-34.


POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>06/01/2014</td>
<td>- Reorganized policy content</td>
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<tr>
<td></td>
<td>- Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:</td>
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<td>- For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)</td>
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<td>- Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans</td>
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<td>- The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage</td>
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<td>- Updated coverage rationale:</td>
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<td>- Reformatted and relocated information pertaining to medical</td>
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