



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Aqueous Shunts and Stents for Glaucoma

**Policy #** 00421

**Original Effective Date:** 05/21/2014

**Current Effective Date:** 09/17/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Ophthalmologic Techniques for Evaluating Glaucoma and Visco canalostomy and Canaloplasty are addressed separately in medical policies 00089 and 00280, respectively.*

### **When Services Are Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider insertion of aqueous shunts approved by the U.S. Food and Drug Administration (FDA) as a method to reduce intraocular pressure (IOP) in patients with glaucoma where medical therapy has failed to adequately control intraocular pressure (IOP) to be **eligible for coverage**.

Based on review of available data, the Company may consider implantation of a single U.S. Food and Drug Administration (FDA)-approved microstent in conjunction with cataract surgery in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication to be **eligible for coverage**.

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of an aqueous shunt for all other conditions, including in patients with glaucoma when intraocular pressure (IOP) is adequately controlled by medications, to be **investigational**.\*

Based on review of available data, the Company considers the use of a microstent for all other conditions to be **investigational**.\*

### **Background/Overview**

Glaucoma surgery is intended to reduce IOP when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts, are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Surgical procedures for glaucoma aim to reduce IOP resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm's canal. In the primary (conventional) outflow pathway from the



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eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm's canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of Schlemm's canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir, which can effectively reduce IOP, but commonly results in filtering "blebs" on the eye, and is associated with numerous complications (eg, leaks or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation, deep sclerectomy, which removes the outer wall of Schlemm's canal and excises deep sclera and peripheral cornea, and viscocanalostomy, which unroofs and dilates Schlemm's canal without penetrating the trabecular meshwork or anterior chamber.

More recently the Trabectome<sup>™</sup>†, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm's canal without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Canaloplasty involves dilation and tension of Schlemm's canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack<sup>™</sup>† illuminated microcatheter (iScience Interventional) to access and dilate the entire length of Schlemm's canal and to pass the suture loop through the canal.

Aqueous shunts may also be placed in the anterior or posterior chamber to facilitate drainage of aqueous humor. Established shunts include the Ahmed<sup>™</sup>† (New World Medical), Baerveldt<sup>®</sup>† (Advanced Medical Optics), Molteno<sup>®</sup>† (IOP), ExPress<sup>®</sup>† mini-shunt (Alco); and the SOLX<sup>®</sup>† DeepLight<sup>®</sup>† Gold Micro-Shunt (SOLX), which shunts aqueous humor between the anterior chamber and the suprachoroidal space. These devices differ depending on explant surface areas, shape, plate thickness, the presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of postoperative infection is less than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is when prior medical or surgical therapy has failed, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Other aqueous stents are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into Schlemm's canal or the suprachoroidal space. These include the iStent<sup>®</sup>† (Glaukos), which is a 1-mm long stent inserted into the end of Schlemm's canal by an internal approach through the cornea and anterior chamber; the second generation iStent *inject*<sup>®</sup>† the third generation iStent *supra*<sup>®</sup>†, which is designed for ab interno implantation into the suprachoroidal space; and the CyPass<sup>®</sup>† (Transcend Medical) suprachoroidal stent.



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## Aqueous Shunts and Stents for Glaucoma

Policy # 00421

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Since aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system are critical for reaching the target IOP. Therefore, some devices may be unable to reduce IOP below the pressure of the distal outflow system used, eg, below 15 mm Hg, and are not indicated for patients for whom very low IOP is desired (eg, those with advanced glaucoma). It has been proposed that stents such as the iStent, Cypass, and Hydrus Microstent may be useful to lower IOP in patients with early stage glaucoma to reduce the burden of medications and problems with compliance. One area of investigation is for patients with glaucoma who require cataract surgery. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than 1 shunt to achieve the desired IOP. Therefore, health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy, complications, and durability of the device.

## FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration

Device	Manufacturer	Type	FDA Status	Date
AquaFlow™ <sup>‡</sup>	Staar Surgical	Drainage device	PMA	2001
Trabectome	NeoMedix	Electrocautery device	510(k)	2006
Ahmed™ <sup>‡</sup>	New World Medical	Aqueous glaucoma shunt	510(k)	< 1993
Baerveldt	Advanced Medical Optics	Aqueous glaucoma shunt	510(k)	< 1993
Krupin	Eagle Vision	Aqueous glaucoma shunt	510(k)	< 1993
Molteno	Molteno Ophthalmic	Aqueous glaucoma shunt	510(k)	< 1993
Ex-PRESS	Alco	Mini-glaucoma shunt	510(k)	2003
iStent	Glaukos	Microstent	PMA	2012
Hydrus™	Ivantis	Microstent	Not approved	
iStent inject	Glaukos	Suprachoroidal stent	Not approved	
iStent <i>supra</i>	Glaukos	Suprachoroidal stent	Not approved	
CyPass	Transcend Medical	Suprachoroidal stent	Not approved	

FDA: Food and Drug Administration; PMA: premarket approval.

The first generation Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno (Molteno Ophthalmic) aqueous shunts received marketing clearance from the FDA between 1989 and 1993; modified Ahmed and Molteno devices were most recently cleared in 2006. Their indication for use is “in patients with intractable glaucoma to reduce IOP where medical and conventional surgical treatments have failed.” The AquaFlow Collagen Glaucoma Drainage Device received premarket approval from FDA in 2001 for the maintenance of subscleral space following nonpenetrating deep sclerectomy. The Ex-PRESS Mini Glaucoma Shunt received 510(k) marketing clearance in 2003. The Ex-PRESS shunt is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb.

In 2012, FDA approved the Glaukos Corporation’s iStent Trabecular Micro-Bypass Stent, PMA P080030, as indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.



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## Aqueous Shunts and Stents for Glaucoma

Policy # 00421

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The labeling describes the following precautions:

1. The safety and effectiveness of the iStent Trabecular Micro-Bypass Stent has not been established as an alternative to the primary treatment of glaucoma with medications. The effectiveness of this device has been demonstrated only in patients with mild to moderate open-angle glaucoma who are currently treated with ocular hypotensive medication and who are undergoing concurrent cataract surgery for visually significant cataract.
2. The safety and effectiveness of the iStent Trabecular Micro-Bypass Stent has not been established in patients with the following circumstances or conditions, which were not studied in the pivotal trial:
  - In children
  - In eyes with significant prior trauma
  - In eyes with abnormal anterior segment
  - In eyes with chronic inflammation
  - In glaucoma associated with vascular disorders
  - In pseudophakic patients with glaucoma
  - In uveitic glaucoma
  - In patients with prior glaucoma surgery of any type, including argon laser trabeculoplasty
  - In patients with medicated IOP greater than 24 mm Hg
  - In patients with unmedicated IOP less than 22 mm Hg nor greater than 36 mm Hg after "washout" of medications
  - For implantation of more than a single stent
  - After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy required, corneal injuries, or complications requiring the placement of an anterior chamber intraocular lens (IOL)
  - When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract

*Note: Use of the iStent has subsequently been reported for many of the circumstances or conditions listed above; most of the publications are case series.*

The SOLX gold shunt and Hydrus Microstent are currently in FDA-regulated trials. They have received regulatory approval in Europe, but are not FDA-approved/cleared for use in the U.S. at this time.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD) for aqueous shunts and stents for glaucoma. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

### **Rationale/Source**

A search of the literature was initially performed on shunts that were in FDA trials at the time. The literature includes aqueous shunts that had been previously cleared by the FDA. The policy has continued to be updated periodically.



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An independent licensee of the Blue Cross and Blue Shield Association.

## Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 09/17/2014

### **FDA-Approved/Cleared Aqueous Shunts**

A 2006 Cochrane review evaluated 15 randomized or pseudo-randomized controlled trials (RCTs), with a total of 1153 participants, on the Ahmed, Baerveldt, Molteno, and Schocket shunts. Trabeculectomy was found to result in a lower mean IOP (by 3.8 mm Hg) than the Ahmed shunt at 1 year. A limitation of this report is that complications were not compared, as the authors considered them to be too variably reported to allow comparative tabulation. There was no evidence of superiority of 1 shunt over another.

A literature review on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices, for an American Academy of Ophthalmology (AAO) technology assessment was published in 2008. This review indicated that the IOP will generally settle at higher levels (approximately 18 mm Hg) with aqueous shunts than after standard trabeculectomy (14-16 mm Hg) or after trabeculectomy with antifibrotic agents 5-fluorouracil or mitomycin C (8-10 mm Hg). In 1 study, mean IOPs with the Baerveldt shunt and adjunct medications were found to be equivalent to trabeculectomy with mitomycin C (13 mm Hg). Five-year success rates for the 2 procedures were found to be similar (50%). The assessment concluded that based on level 1 evidence, aqueous shunts were comparable with trabeculectomy for IOP control and duration of benefit. The risk of postoperative infection was less with aqueous shunts than after trabeculectomy. Complications of aqueous shunts were noted to include: immediate hypotony after surgery; excessive capsule fibrosis and clinical failure; erosion of the tube or plate edge; strabismus; and, very rarely, infection. The most problematic long-term consequence of anterior chamber tube placement was described as accelerated damage to the corneal endothelium over time.

A comparative effectiveness review (CER) on glaucoma treatments was prepared by the Johns Hopkins Evidence-based Practice Center for the Agency for Healthcare Research and Quality in 2012. The CER found that the data available on the role of aqueous drainage devices in open-angle glaucoma (primary studies, systematic review) were inadequate to draw conclusions on the comparative effectiveness of these treatments in comparison with laser and other surgical treatments.

### Baerveldt Glaucoma Shunt

Early results from the open-label multicenter randomized Tube Versus Trabeculectomy (TVT) study were reviewed in the 2008 AAO technology assessment, and in 2012, Gedde et al reported 5-year follow-up from this study. The study included 212 eyes of 212 patients (18-85 years) who had previous trabeculectomy and/or cataract extraction with IOL implantation and uncontrolled glaucoma with IOP of 18 mm Hg or greater and 40 mm Hg or lower on maximum tolerated medical therapy. Excluding patients who had died, the study had 82% follow-up at 5 years, with a similar proportion of patients in the tube and trabeculectomy groups. At 5 years, neither IOP (14.3 mm Hg in the tube group and 13.6 mm Hg in the trabeculectomy group) nor number of glaucoma medications (1.4 in the tube group and 1.2 in the trabeculectomy group) were significantly different with intention-to-treat analysis. The cumulative probability of failure over the 5 years was lower in the tube group than the trabeculectomy group (29.8% vs 46.9%), and the rate of reoperation was lower (9% vs 29%). The rate of loss of 2 or more lines of visual acuity was similar in the 2 groups (46% in the tube group and 43% in the trabeculectomy group).



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Current Effective Date: 09/17/2014

### Ex-PRESS Mini Shunt

A 2014 publication described a U.S. multicenter randomized trial of trabeculectomy compared with EX-PRESS implantation in 120 patients (120 eyes).<sup>5</sup> The groups were comparable at baseline, with a preoperative IOP of 25.1 mm Hg on a mean of 3.1 medications for the EX-PRESS group, compared with 26.4 mm Hg on a mean of 3.1 medications in the trabeculectomy group. Throughout 2 years of follow-up after surgery, the average IOP and number of medications were similar in the 2 groups. At 2 years, mean IOP was 14.7 mm Hg on 0.9 medications in the EX-PRESS group and 14.6 mm Hg on 0.7 medications in the trabeculectomy group. Surgical success was 90% and 87% at 1 year and 83% and 79% at 3 years in the EX-PRESS and trabeculectomy groups, respectively. Visual acuity returned to near baseline levels at 1 month after EX-PRESS implantation and 3 months after trabeculectomy ( $p=0.041$ ), with a median time to return to baseline vision of 0.7 months and 2.2 months, respectively. Postoperative complications were higher after trabeculectomy (41%) than after EX-PRESS implantation (18.6%).

In 2009, de Jong reported a randomized study of the EX-PRESS mini shunt compared with standard trabeculectomy in 78 patients (80 eyes) with a diagnosis of open-angle glaucoma that could not be controlled with maximal-tolerated medical therapy.<sup>6</sup> Five-year follow-up was reported in 2011.<sup>7</sup> The 2 groups were similar after randomization, with the exception of difference in the mean age (62 years for the EX-PRESS group, 69 years for the trabeculectomy group). At an average 12 months' follow-up, mean IOP had improved from 23 to 12 mm Hg in the EX-PRESS group and from 22 to 14 mm Hg in the trabeculectomy group. Both groups of patients used fewer antiglaucoma medications postoperatively than before the procedure (from 2.8 at baseline to 0.3 in the EX-PRESS group and from 3.0 at baseline to 0.6 in the trabeculectomy group). Twelve-month Kaplan-Meier success rates (defined as an IOP of  $>4$  mm Hg and  $\leq 18$  mm Hg without use of antiglaucoma medications) were 82% for the EX-PRESS shunt and 48% for trabeculectomy. At 5 years, the success rates were not significantly different between the 2 groups. In the EX-PRESS group, IOP remained stable from year 1 (12.0 mm Hg) to year 5 (11.5 mm Hg), while in the trabeculectomy group, IOP decreased from year 3 (13.5 mm Hg) to year 5 (11.3 mm Hg). There were more complications after trabeculectomy than after EX-PRESS implantation.

### iStent

Results from the iStent U.S. investigational device exemption (IDE) open-label 29 site multicenter randomized clinical trial were reported to the FDA in 2010, with 1-year results published in 2011 and 2-year results published in 2012. The objective of the trial was to measure the incremental effect on IOP from iStent implantation over that of cataract surgery alone and to determine the potential benefit of combining 2 therapeutic treatments into 1 surgical event. A total of 240 patients (mean age, 73 years) with cataracts and mild to moderate open-angle glaucoma (IOP  $\leq 24$  mm Hg controlled on 1-3 medications) underwent a medication washout period. Patients were randomized to undergo cataract surgery with iStent implantation or cataract surgery only if the unmedicated IOP was 22 mm Hg or higher and 36 mm Hg or lower. The mean number of medications at baseline was 1.5. The medicated IOP at baseline was 18.7 mm Hg in the stent group and 18.04 in the control group. After washout, the mean IOP was 25 mm Hg and mean visual acuity (logMAR) was 0.36. Follow-up visits were performed at 1, 3, 6, and 12 months. Results were assessed by intention-to-treat analysis with the last observation carried forward and per protocol analysis. Of the 117 subjects randomized to iStent implantation, 111 underwent cataract surgery with stent implantation, and 106 (91%) completed the 12-month postoperative visit. Of the 123 subjects randomized to



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Policy # 00421

Original Effective Date: 05/21/2014

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cataract surgery only, 117 underwent cataract surgery and 3 exited the study because of complications of cataract surgery. Of the remaining 114 subjects, 112 (91%) completed the 12-month visit. The proportion of eyes meeting both the primary (unmedicated IOP  $\leq$  21 mm Hg) and secondary outcomes (IOP reduction  $\leq$  20% without hypotensive medications) was higher in the treatment group than in the control group through 1-year follow-up. At 1-year follow-up, 72% of treatment eyes and 50% of control eyes achieved the primary efficacy end point. The proportion of patients achieving the secondary efficacy end point at 1 year was 66% in the treatment group versus 48% in the control group. Ocular hypotensive medications were initiated later in the postoperative period and used in a lower proportion of patients in the treatment group throughout 1-year follow-up (eg, 15% vs 35% at 12 months). The mean reduction in IOP was similar in the 2 groups, with a slightly higher level of medication used in the control group (mean, 0.4 medications) in comparison with the treatment group (0.2 medications) at 1 year.

At 2-year follow-up, there were 199 of the original 239 patients (83%) remaining in the study. The primary end point, IOP of 21 mm Hg or less without use of medication, was reached by 61% of patients in the treatment group compared to 50% of controls ( $p = 0.036$ ). The secondary outcomes of IOP reduction of 20% or more without medication (53% vs 44%) and mean number of medications used (0.3 vs 0.5) were no longer significantly different between the groups at 2 years. As noted by the FDA, this study was conducted in a restricted population of patients who had an unmedicated IOP of 22 mm Hg or higher and 36 mm Hg or lower. The results of this study indicate that treatment of this specific population with a microstent is likely to improve outcomes at 1 year compared to cataract surgery alone. However, given the 2-year results of this study, it is not possible to conclude with certainty that health outcomes are improved at longer periods of follow-up.

In 2010, Fea reported a randomized double-blind clinical trial of cataract surgery with or without iStent implantation (2:1 ratio) in 36 patients. Inclusion criteria were a previous diagnosis of primary open-angle glaucoma with an IOP above 18 mm Hg at 3 separate visits, and on 1 or more hypotensive medications. The stent was implanted using the same small temporal clear corneal incision (approximately 3.0 mm) that had been used for phacoemulsification and intra-ocular lens placement and was guided into Schlemm's canal by an applicator and ab interno gonioscopy. Follow-up visits with investigators who were masked to the treatment condition were conducted at 24 hours, 1 week, and 1, 2, 3, 6, 9, 12, and 15 months. Prescription of hypotensive medications was performed according to preset guidelines. Primary outcomes were IOP and reduction in medication use over 15 months and IOP after a 1-month washout of ocular hypotensive agents (16 months postoperatively). At baseline, IOP was an average of 17.9 mm Hg with 2.0 medications in the stent group and 17.3 mm Hg with 1.9 medications in the control group. The mean IOP at 15 months was 14.8 mm Hg, with 0.4 medications in the stent group and 15.7 mm Hg with 1.3 medications in the control group. Eight patients in the stent group (67% of 12) and 5 in the control group (24% of 21) did not require ocular hypotensive medication. The authors commented that patient compliance is an ongoing concern for most ophthalmologists; therefore, a main goal is to keep the patient as free as possible from medications postoperatively. After washout of medications, mean IOP was 16.6 in the stent group and 19.2 in the control group. Two stents were malpositioned, but one of these appeared to be functioning, and there were no reported adverse events related to stent implantation. This small study suggests that without hypotensive medication, the iStent lowers IOP by about 2.5 mm Hg beyond that generated by cataract surgery alone (approximately 25% decrease in the risk of glaucomatous progression).

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Page 7 of 11



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 09/17/2014

Use of multiple iStents in combination with cataract surgery was reported in an open-label prospective series of 53 eyes (47 patients) in 2012. Of the 53 eyes, 28 had implantation of 2 stents and 25 had implantation of 3 stents, based on the need for greater IOP control, as determined by the operating surgeon. Best-corrected visual acuity (BCVA) improved or remained stable in 89% of eyes. IOP decreased from a mean of 18.0 mm Hg to 14.3 mm Hg, and the number of hypotensive medications decreased from a mean of 2.7 to 0.7 at 1 year postoperatively. Target IOP was reached in 77% of eyes, while 59% of patients discontinued use of all medications in the study eye. At 1 year, the mean number of hypotensive medications decreased to 1.0 in the 2-stent group and 0.4 in the 3-stent group. Medication use had been stopped in 46% of eyes in the 2-stent group compared to 72% in the 3-stent group. Stent blockage occurred in the early postoperative period in 15% of eyes and was successfully treated with laser.

### Aqueous Shunts and Stents Not Approved by the FDA

#### *iStent inject*

An industry-sponsored multicenter unblinded randomized trial compared implantation of 2 iStent *inject* devices versus 2 ocular hypotensive agents.<sup>13</sup> The 192 patients enrolled in this unmasked trial had an IOP that was not controlled by 1 hypotensive medication. At 12-month follow-up, the 2 groups were comparable for IOP reduction of at least 20%, IOP of 18 mm Hg or less, and mean decrease in IOP. A greater proportion of patients in the iStent *inject* group achieved an IOP reduction of at least 50% (53.2% vs 35.7%). One patient in the iStent *inject* group experienced elevated IOP (48 mm Hg) and 4 required ocular hypotensive medication. Longer-term studies are in progress.

#### Other

Case series have been identified on the EyePass and CyPass microstent.<sup>14,15</sup> The CyPass has not received FDA approval/clearance at this time. The EyePass is no longer being developed.

### Ongoing and Unpublished Clinical Trials

Searches for aqueous shunts and glaucoma at online site [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) found a number of clinical trials in progress.

### Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty societies and 2 academic medical centers while this policy was under review in 2013. The input supported use of aqueous shunts in patients with moderate to severe glaucoma uncontrolled by medication. Input supported use of a single microstent in patients with mild to-moderate glaucoma undergoing cataract surgery to reduce side effects of medications and to avoid noncompliance.





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## Aqueous Shunts and Stents for Glaucoma

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### Summary

Randomized controlled trials have shown that the use of large externally placed shunts with extraocular reservoirs results in success rates as good as standard filtering surgery (trabeculectomy). Shunts have a different side effect profile and avoid some of the most problematic complications of trabeculectomy. Therefore, use of FDA-approved shunts may be considered medically necessary as a method to reduce IOP in patients with glaucoma in whom medical treatments have failed to adequately control IOP. Aqueous shunts that are not FDA-approved/cleared, as well as all conditions for the approved devices aside from reducing IOP in patients with glaucoma in whom medical therapy has failed, are considered investigational.

Use of microstents has been studied in patients with both cataracts and less advanced glaucoma, where the IOP is at least partially controlled with medication. Results from these studies indicate that IOP may be lowered below baseline with decreased need for medication although the benefit appears to diminish after the first year. A microstent has received FDA approval for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. Based on the documented reduction in the need for medications and the clinical input received on this policy, use of a single FDA-approved microstent may be considered medically necessary when implanted concurrently with cataract surgery.

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Page 9 of 11



# BlueCross BlueShield of Louisiana

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## Aqueous Shunts and Stents for Glaucoma

Policy # 00421

Original Effective Date: 05/21/2014

Current Effective Date: 09/17/2014

14. Fea AM, Belda JI, Rekas M, et al. Prospective unmasked randomized evaluation of the iStent inject ((R)) versus two ocular hypotensive agents in patients with primary open-angle glaucoma. *Clin Ophthalmol*. 2014;8:875-882. PMID 24855336
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## Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	66180, 66183, 0191T, 0253T
HPCS	C1783
ICD-9 Diagnosis	365.00 thru 365.9
ICD-9 Procedure	No codes

## Policy History

Original Effective Date: 05/21/2014

Current Effective Date: 09/17/2014

05/01/2014 Medical Policy Committee review

05/21/2014 Medical Policy Implementation Committee approval. New policy.

09/04/2014 Medical Policy Committee review

09/17/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2015

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

**\*\*Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.