KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Glaucoma Surgical Procedures

- Canaloplasty
- Microinvasive Glaucoma Surgery (MIGS)

Criteria

For Medicare Members

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<tr><th>Source</th><th>Policy</th></tr>
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<tr><th>Service</th><th>Criteria</th></tr>
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For Non-Medicare Members

Service	Criteria
Canaloplasty	Canaloplasty is covered when all of the following criteria have been met: 1. Diagnosis of glaucoma with eye pressures inadequately controlled on maximum tolerated topical medications and laser treatment 2. Documented risk for greater problems with standard glaucoma surgery (trabeculectomy or valve implant) as defined by one of the following: • Myopic diopters greater than 5 • Hyperoptic diopters greater than 3 • Moderate to severe dry eye • Blepharitis

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	• Preservative allergy • Has allergy or side effects preventing the use of one or more of the standard glaucoma eye drops • Had problems with trabeculectomy or glaucoma valve implant surgery in the contralateral eye (such as bleb dysesthesia (chronic eye pain) or need for re-operation) •
Microinvasive Glaucoma Surgery (MIGS)	***iStent Device and Hydrus* –** 66989, 66991 iStent Device and Hydrus will be considered medically necessary when **ALL of the following** are met: 1. Only used in conjunction with Cataract Surgery when the individual is currently being treated with an ocular hypotensive medication **AND/OR** had prior laser trabeculoplasty 2. Used to reduce intraocular pressure (IOP) of greater than 21, except when clinical circumstances would support a lower IOP (this rationale should be documented in the note) 3. 18 years old or over **AND** 4. Mild to Moderate primary open-angle glaucoma defined as how much vision loss via visual field testing 5. Eyes do **NOT** have the following* a. Prior significant trauma b. In eyes with abnormal anterior segment c. In eyes with chronic inflammation d. In glaucoma associated with vascular disorders e. In pseudophakic patients with glaucoma f. In uveitic glaucoma g. In eyes with prior incisional glaucoma surgery or cilioablative procedures h. In eyes with prior laser trabeculoplasty (LT) with selective LT within 90 days prior to screening or prior argon laser trabeculoplasty (ALT) at any time i. In patients with unmedicated IOP greater than 36 mmHg after “washout” of medications j. Plan for implantation of more than two stents k. 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 IOL l. When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract Contraindicated in the following patients: • In eyes with angle-closure glaucoma. • In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle. • In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure *Exclusions include clinical circumstances that were not tested in the initial FDA approval.
	Xen Gel Implant – 0449T, 66183

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	The use of Xen Gel Implant will be considered medically necessary when **ONE of the following** are met: 1. Refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues) **OR** 2. Previous surgical treatment has failed (angle-based procedures, laser trabeculoplasty) **OR** 3. Primary open-angle glaucoma **OR** 4. Pseudo-exfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy Should **NOT** be used if any of the following are met: a. Angle-closure glaucoma where the drainage angle of the eye has not been surgically open b. Glaucoma drainage device previously implanted c. Presence of conjunctival scarring, prior conjunctival surgery or other conjunctival pathologies (e.g., pterygium) in the target quadrant d. Pathologies of the conjunctiva (clear membrane covering the white outer layer of the eye) in the area needed for this implant Active iris neovascularization or neovascularization of the iris within six months of the surgical date (abnormal formation of new blood vessels on the iris) e. Eye inflammation (e.g., conjunctivitis, keratitis, uveitis) f. Artificial lens implanted in the anterior chamber (intraocular lens) g. Presence of intraocular silicone oil h. Vitreous present in the anterior chamber
	Cypass Device – 0474T The Cypass device was taken off the market on 8/29/2018 by the manufacturer due to safety concerns. This device will no longer be covered for Kaiser Permanente members.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Canaloplasty

Glaucoma is a common eye disease caused by elevated intraocular pressure (IOP) that leads to optic nerve damage and visual field loss. Glaucoma is frequently referred to as the “silent thief of sight” because it is not usually associated with ocular or systemic symptoms but can cause irreversible blindness if left undiagnosed and untreated. It is estimated that over 2 million people in the United States have glaucoma, 80,000 of whom are legally blind as the result of the disease (Lee 2005).

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Glaucoma has been classically categorized into primary or secondary angle-closure glaucoma (closure of the anterior chamber angle), and primary or secondary open-angle glaucoma (where the anterior chamber angle of the eye remains open). The condition is considered primary if the eye has no pre-existing disease and secondary in an eye with a pre-existing disease. Primary open-angle glaucoma is the most common type in the US. It occurs insidiously and is usually asymptomatic in its early stages. In the later stages, when the optic nerve is damaged, the patient experiences progressive worsening of vision, and eventually peripheral followed by central visual loss (Lee 2005, Rotchford 2005).

The treatment goal for patients with glaucoma is preventing functional vision loss by lowering the IOP to a level where progressive glaucomatous optic neuropathy is stopped, or at least slowed. Conventional treatment usually begins with the use of topical IOP-lowering agents. These include beta-blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, cholinergic, and prostaglandin analogs. Laser trabeculoplasty has also been used to further lower the IOP to decrease or eliminate the need for antiglaucoma medications. Incisional filtering surgery is considered if the patient's IOP cannot be reduced with the maximal tolerated medical therapy, laser trabeculoplasty or a combination of both. Trabeculectomy is a filtration surgical procedure commonly used to lower the IOP. The procedure involves creating an opening in the anterior chamber angle to allow the aqueous humor flow from the anterior chamber into a space beneath the conjunctiva under the surface of the eye. A successful trabeculectomy procedure is marked by an elevated conjunctival zone, the bleb, where the aqueous gathers in pockets prior to absorption into the surrounding blood vessels and lymphatics. Trabeculectomy with or without antimetabolites can successfully control IOP, but not without risks. It may be associated with numerous intraoperative or postoperative complications including hypotony, bleb leaks, bleb infections /endophthalmitis, hyphaema, loss of visual acuity, increased risk of cataract formation, scar tissue which causes obstruction of the channel created and in turn blocking the drainage of the aqueous humor, and several other complications (Lee 2005, Rotchford 2005, Lewis 2007).

Nonpenetrating glaucoma procedures were first introduced in the late 1950s and early 1960s, and revived in the 1980s and 1990s, as alternatives to standard filtration surgeries for controlling IOP in open-angle glaucoma without penetration of the intraocular space. These procedures include deep sclerectomy with and without an implant, and viscocanalostomy. The latter is performed by several techniques that basically involve the production of superficial and deep scleral flaps, excision of the deep scleral flap to create a scleral reservoir, and unroofing of Schlemm's canal. An ophthalmic viscoelastic device is then injected into the deep scleral lake and toward the cut ends of Schlemm's canal to open it and create a passage from the scleral reservoir to the canal. The superficial scleral flap is then sutured water tight trapping the viscoelastic until healing takes place (Filippopoulos 2008, Green 2007, Noureddin 2006).

Recent advances in technology, ocular ultrasound, and viscoelastics have led to the development of canaloplasty as a promising nonpenetrating surgical technique for lowering the IOP in patients with open-angle glaucoma. The procedure aims at increasing the flow of aqueous humor from the anterior chamber through the trabecular meshwork and Descemet's window into and around the Schlemm's canal and out through the collector channels, thus reducing the IOP by restoring the trabeculocanalicular outflow pathway. The procedure utilizes the full 360 degrees of the canal and outflow system without creating a fistula or need for a bleb. Unlike viscocanalostomy, canaloplasty aims at opening the entire length of the canal rather than opening only a section of it. Canaloplasty uses viscoelastic and specialized flexible microcatheter with an illuminated tip (iScience surgical Ophthalmic Microcannula) to forcibly open the Schlemm's canal (Lewis 2006, 2007, Godfrey 2009).

Similar to viscocanalostomy, canaloplasty is completed under a scleral flap. A one-half thickness parabolic shaped scleral flap is dissected. A deep flap is then dissected down to a depth very close to the ciliary body/choroid and carefully carried forward anteriorly until the Schlemm's canal is unroofed. The canal is identified and intubated with a cannula which has a lighted tip to identify its location as it passes through the canal. The cannula has a lumen to allow for the passage of viscoelastic for dilatation of the canal. Once it has passed the full length of Schlemm's, a 10-0 Prolene suture is tied to the cannula which is then withdrawn leaving the suture in its place. Tying off the suture provides tension that holds the canal open. The scleral flap is then tightly closed as well as the conjunctiva. The procedure is usually performed under special ultrasound imaging to help identify the canal and its instrumentation (Lewis 2006, 2007).

Canaloplasty has a steep learning curve. Identifying and entering the Schlemm's canal, inserting the catheter, placing the tension suture, and providing the right tension in the suture depend on the surgeon's skill and experience. The outcome of the surgery also depends on the selection of the patients; those who had previous trabeculectomies with scarring in the canal are not good candidates. According to the authors of a review article, the ideal candidates would be patients who cannot have a bleb because they wear contact lenses, have a dry

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eye, or for cosmetic reasons. The procedure is contraindicated in patients with angle recession, neovascular glaucoma, chronic angle closure, narrow-angle glaucoma, narrow inlets with plateau iris, and in patients with previous surgery which would prevent 360o catheterization of Schlemm's canal (Lewis 2006, Godfrey 2009).

In June 2008 The FDA cleared the iScience Interventional Canaloplasty Microcatheter for marketing for catheterization and vasodilatation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

Microinvasive

The term micro-invasive or minimally invasive glaucoma surgery (MIGS) refers to a group of newer surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance and involve minimal trauma to ocular tissues. In contrast to external filtration surgeries such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries. Compared with traditional filtration surgery, MIGS holds the promise of faster recovery time and less severe complications.

It is this potentially improved safety profile that opened up the indications for MIGS to include patients with early-stage glaucoma to reduce the burden of medications and problems with compliance (due to eye drop application difficulty, cost, cosmetic effects, and frequency). Another area of investigation is 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. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

There are three FDA approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July 2016), and the XEN Glaucoma Treatment System (Nov 2016). The iStent is a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted into Schlemm's canal to augment the natural outflow system. CyPass is a 6.35 mm long fenestrated microstent made of biocompatible polyimide inserted into the supraciliary space, thus using an alternative outflow system. The XEN45 is a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space, bypassing the natural outflow system.

Both iStent and CyPass were FDA approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate OAG and a cataract that are currently being treated with medication to reduce IOP. XEN45 was granted FDA clearance for the management of refractory glaucoma, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

Canaloplasty

10/06/2008: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine that canaloplasty has the same or better effect than medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty has the same or better effect than filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer for the patient than filtration surgical interventions as trabeculectomy.

Articles: The search yielded only two studies on canaloplasty: Lewis 2007, and Shingleton 2008. Both were prospective case series with no comparison or control groups. Lewis and colleagues reported the interim results of canaloplasty performed on 94 patients with open-angle glaucoma. Shingleton et al reported one-year results of canaloplasty combined with cataract surgery performed on 54 patients with open-angle glaucoma and cataract. The authors of the latter study were co-authors in the first study. Both studies involved the same 14 clinical sites and same group of ophthalmologists. It appears also that there could be an overlap of the patients participating in the two studies. Both reported on one-year results. The published case series with the larger population size was selected for critical appraisal. Lewis R A, von Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults. Interim clinical study analysis. J Cataract Refrat Surg 2007; 33:1217-1226. See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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10/05/2009: MTAC REVIEW
Canaloplasty
Evidence Conclusion*:* There is insufficient evidence to determine that canaloplasty is better than or equivalent to medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is better than or equivalent to filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer than filtration surgical interventions as trabeculectomy.
Articles: The search yielded only one more recent report (Lewis et al 2009) on the 2-year results of the same case series on canaloplasty that was published earlier in 2007 and reviewed by MTAC in 2008. No randomized or nonrandomized controlled trials comparing canaloplasty to another treatment or intervention were identified. The new report by Lewis and colleagues (2009) was critically appraised. Lewis R A, von Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults. Two-year interim clinical study results. J Cataract Refrat Surg 2009; 35:814-824 See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/08/2019: MTAC REVIEW
XEN Gel Implant (XEN® Gel stent) for Glaucoma
Conclusion:

- There is no published high-quality evidence from randomized controlled trials (to date) to determine the comparative effectiveness and safety of XEN Gel implantation versus trabeculectomy or other minimally invasive procedure used to lower IOP in patients with open angle glaucoma uncontrolled with optimal local medications.

- Low quality evidence from several prospective and retrospective observational studies suggest that XEN Gel implant lowers the IOP and reduces the number of IOP- lowering medication used in selected patients with open angle glaucoma uncontrolled with optimal local medications. The results, however, must be interpreted with caution due to the non-randomized design, potential confounding, and other inherent limitations of observational studies.

- The success rates varied between studies from 37-68% depending on definition of success based on the level of IOP reached, duration of follow up, use of topical medications, and need for revision surgeries.

- XEN Gel implant is associated with intra-and post- operative adverse events (AEs). Many were reported to resolve spontaneously without the need for intervention. However, few were serious and /or required immediate and inevitable interventions.

- More than one third of the eyes require additional surgeries after XEN Gel implant.

Articles: The literature search did not identify any randomized controlled trials that compared the safety and efficacy of XEN45 Gel implant versus trabeculectomy or any other surgical procedure. The search revealed 3 systematic reviews with meta-analyses that pooled the results of the different of MIGS procedures, two studies (published in 3 articles on the earlier generations of the implant (XEN140 and XEN 63), around 10 observational studies with pre-post comparisons after XEN45 Gel implant with or without cataract surgery, and one retrospective observational study that compared the results the microstent implant to those of a trabeculectomy procedure.

The meta-analyses of studies on MIGS as well as the studies using the earlier generations of XEN Gel (60 and 140) were excluded. The observational study with a comparison group (Schlenker, 2017) was critically appraised (Evidence table 1) and the larger prospective and retrospective observational studies were summarized in a following table. See Evidence Table.

The use of Xen Gel Implant as a surgical treatment for glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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Canaloplasty
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Medicare – Medical Necessity Review not required

CPT® Codes	Description
66174	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent

***Xen Gel* - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® Codes	Description
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

***iStent and Hydrus* - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® Codes	Description
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

Considered not medically necessary:

CPT® Codes	Description
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

Cypass (no longer available) - Considered not medically necessary:

CPT® Codes	Description
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date	Date Reviewed	Date Last

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Created		Revised
02/06/2018	02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC] , 02/07/2023[MPC], 08/06/2024[MPC]	08/02/2024

[MPC] Medical Policy Committee

Revision History	Description
06/05/2018	MPC approved criteria for commercial members
10/08/2018	Non-coverage language for the Cypass device
11/14/2018	Language regarding iStent added
08/06/2019	MTAC review for Xen Gel was added
11/15/2019	Added all requests for Xen Gel must go to Medical Director for review
04/07/2020	MPC approved to adopt new coverage criteria for Xen Gel & iStent/Hydrus as surgical treatments for glaucoma, effective 08/01/2020.
08/12/2020	Removed Non-Medicare criteria prior to 08/01/2020
01/27/2022	Updated applicable coding (removed deleted codes 0191T, 0376T, added 66989, 66991, 0671T)
11/13/2023	Updated Medicare coverage article link (A57864).
08/02/2024	Merge MIGS & Canaloplasty criteria- Glaucoma Surgical Procedures

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