Regence

Medical Policy Manual Surgery, Policy No. 227

Surgical Treatments for Glaucoma

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Glaucoma is usually caused by fluid build-up in the eye, which leads to optic nerve damage. Various minimally invasive techniques are available to treat glaucoma, including excimer laser trabeculostomy (also known as excimer laser trabeculotomy), femtosecond laser trabeculotomy, transciliary fistulization, minimally invasive micro sclerostomy or trabeculostomy, and travoprost drug eluting ocular implants.

MEDICAL POLICY CRITERIA

Note: This policy does *not* address other procedures treating glaucoma (e.g., laser trabeculoplasty, trabeculectomy, aqueous stents or shunts).

The following devices and procedures for treatment of glaucoma are considered **investigational:**

A. Excimer laser trabeculostomy or trabeculotomy
B. Femtosecond laser trabeculotomy
C. Transciliary fistulization
D. Minimally invasive micro sclerostomy or trabeculostomy

E. Travoprost drug eluting ocular implants (e.g. iDose®TR)

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Optical Coherence Tomography (OCT) of the Anterior Eye Segment, Medicine, Policy No. 133

BACKGROUND

GLAUCOMA SURGERY

Glaucoma is characterized by elevated intraocular pressure (IOP), which results in visual field loss and irreversible blindness if left untreated. In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork (TM), enters a space lined with endothelial cells (Schlemm canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of the Schlemm canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk. Surgical procedures for glaucoma aim to reduce IOP resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm's canal. These procedures may be indicated where medical therapy has failed to adequately control the IOP.

PRIMARY OPEN ANGLE GLAUCOMA TREATMENTS

Drug Therapy to Control IOP

Examples of drugs that may be prescribed include, but are not limited to, alpha-agonist, beta blockers, carbonic-anhydrase inhibitors, miotic agents and prostaglandin analogs.

Surgical Care

Laser Trabeculoplasty

A laser is used to burn small areas of the trabecular meshwork (where normal drainage of the eye occurs) to increase aqueous fluid outflow, thereby lowering IOP.

Incisional or Filtering Surgery (trabeculectomy or drainage implants)

Trabeculectomy (guarded filtration surgery) is a commonly performed surgical procedure for lowering IOP in glaucoma where medications cannot adequately control the pressure. In trabeculectomy, a fistula is created under a scleral flap and in the trabecular meshwork and adjacent structures to allow drainage of aqueous humor from the anterior chamber into a subconjunctival filtering bleb. However, trabeculectomy is associated with significant complications (e.g., leaks or bleb-related endophthalmitis) and long-term failure; therefore, other surgical interventions that aim to facilitate drainage of aqueous humor and reduce IOP have been developed, including aqueous shunts, micro-stents, and laser surgeries, such as selective laser trabeculoplasty and iridotomy.

Excimer laser trabeculostomy/trabeculotomy (ELT) and femtosecond laser trabeculotomy (FLT) are techniques that use lasers to create channels through the TM and into the Schlemm's canal. ELT requires a corneal incision and uses a 308-nm xenon chloride excimer

laser in combination with a fiber optic delivery system to produce 200-µm trabeculostomy openings.[1] FLT uses laser pulses through the cornea and across the anterior chamber to create channels through the trabecular meshwork and does not require corneal incision.

Cycloablation

This technique is also known as ablation of the ciliary body but is usually considered a last resort option due to the permanent destruction of the ciliary body.

Transciliary Fistulization (Transciliary Filtration, Singh Filtration)

Transciliary fistulization for the treatment of glaucoma is an approach to filtering surgery. A thermocauterization device called the Fugo Blade is used 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. Plasma ablation with the Fugo Blade allows the highly vascular ciliary body to be penetrated with little or no bleeding. Aqueous fluid drains from the posterior chamber of the eye (in contrast to conventional filtering surgeries in which aqueous fluid is filtered from the anterior chamber).

Minimally Invasive Micro Sclerostomy or Trabeculostomy

Minimally invasive micro sclerostomy (MIMS) is an ab interno stentless, subconjunctival filtration procedure used to create a sclerocorneal drainage channel for reduction of IOP. The MIMS surgical system by Sanoculis is inserted through a small incision to make a permanent drainage tunnel, allowing extra fluid to continuously flow out of the eye and lower eye pressure.

Drug Eluting Ocular Implants

A variety of sustained-release drug eluting ocular implants are being developed as alternatives to topical delivery of iop-lowering medications requiring daily dosing. These include travoprost (a prostaglandin analog) eluting intracameral implants (e.g., iDose®TR).

REGULATORY STATUS

There are currently no ELT, FLT, or MIMS devices that are approved by the U.S Food and Drug Administration (FDA). The ExTra ELT laser platform and MIMS system are available in Europe.

The Fugo Blade (Medisurg Ltd.) received the FDA 510(k) approval in October 2004 for sclerostomy for the treatment of primary open-angle glaucoma where maximum tolerated medical therapy and trabeculoplasty have failed.

The iDose®TR (Glaukos) was granted a New Drug Application (NDA) approval from the FDA in December 2023 (NDA# 218010).[2] The iDose TR is indicated for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension. The iDose®TR contains 75 mcg of travoprost pre-loaded in a single-dose inserter which is administered intracamerally through a small, clear corneal incision and is anchored into the sclera at the iridocorneal angle. The iDose®TR should not be readministered to an eye that received a prior iDose®TR. The iDose®TR (travoprost intracameral implant) is contraindicated in patients with:

- active or suspected ocular or periocular infections.
- corneal Endothelial Dystrophy (e.g., Fuch’s Dystrophy, corneal guttatae).

- prior corneal transplantation, or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]).
- hypersensitivity to travoprost or to any other components of the product.

EVIDENCE SUMMARY

EXCIMER LASER TRABECULOSTOMY

Systematic Reviews

Durr (2020) published a review of the evidence for ELT that included eight published studies: one randomized controlled trial (RCT), two prospective case series, and five retrospective case series, as well as two studies that were not yet published: a retrospective observational study that has since been published and a prospective observational study that has not.[1] The RCT, published by Babighian (2010), compared ELT (n=15) to selective laser trabeculoplasty (SLT, n=15) and reported complete and qualified success rates that were not significantly different between groups at two years (53% for ELT vs. 40% for SLT, p=0.35, and 33.3% for ELT vs. 26.6% for SLT, respectively).[3] The review did not evaluate the quality of the included studies. The authors noted the RCT's small sample size and concluded that while "current available evidence show an IOP-lowering effect from ELT alone or in combination with cataract surgery with encouraging results across different studies and patient populations, […] more studies are needed to better characterize ELT and further substantiate these promising results."

A systematic review and meta-analysis by Lavia (2017) assessed the evidence for different minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma.[4] The review included nine RCTs and 21 case series that evaluated a number of procedures and devices, including ELT. Only studies with at least 12 months of follow-up were included, and the primary outcome was change in both IOP and the use of glaucoma medications at 12 months. The studies of ELT included in the review were the RCT by Babighian (2010)[3] and two observational studies.[5, 6] The RCT was judged to be at low risk of bias for all domains except allocation concealment, which was at unclear risk, while the observational studies were both judged to have serious risk of bias in at least one domain. The meta-analysis indicated that MIGS were associated with a decrease of IOP and a reduction of glaucoma medications and that these procedures had a low complication rate, but it also noted substantial heterogeneity between studies.

Randomized Controlled Trials

No additional RCTs beyond the trial included in the reviews above were identified.

Nonrandomized Studies

No nonrandomized controlled trials published since the systematic reviews above were identified.

A retrospective review of combined ELT and phacoemulsification procedures performed at a clinic in Spain was published by Papa-Vettorazzi (2023).[7] One-year follow up data from 37 eyes showed a reduction in IOP from 17.76 ± 4.88 mmHg to 15.35 ± 3.10 mmHg. The authors reported that the procedure was a complete success in 17.7% of eyes and a qualified success in 54.8%.

Berlin (2022) published a retrospective review of ELT procedures performed at a single institution.[8] This included 164 eyes, 90 treated with ELT alone and 74 treated with a combination of ELT and phacoemulsification. IOP went from 22.17 ± 7.0 mm Hg to 16.84 ± 5.2 mm Hg at one year (n = 69) in the ELT-only group, and in the 19 eyes with eight-year follow-up data, this reduction was maintained. Similar results were seen in the combination treatment group.

A study by Deubel (2021) included 87 patients that underwent ELT without cataract surgery.[9] There was an IOP reduction of almost 30% after the first year and almost 24% after two years. IOP generally increased from the post-operative result through three years. After a median follow-up of 656 days, 66% of these patients did not require another IOP-lowering intervention. There was no reduction in the number of glaucoma medications at the final follow-up.

FEMTOSECOND LASER TRABECULOTOMY

Systematic Reviews

No systematic reviews were identified on femtosecond laser trabeculotomy.

Randomized Controlled Trials

No RCTs were identified on femtosecond laser trabeculotomy.

Nonrandomized Studies

Nagy (2023) published the results of a first-in-human safety study of femtosecond laser image-guided trabeculotomy in 12 patients (18 eyes).[10] At 24 months following the procedure, the mean IOP was reduced by 34.6% from 22.3 ± 5.5 to 14.5 ± 2.6 mmHg ($p< 5e^{-5}$). No serious adverse events were reported.

TRANSCILIARY FISTULIZATION

Systematic Reviews

A systematic review by Lavia (2017), discussed earlier, also included transciliary fistulization.[4] However, there were no RCTs that evaluated the Fugo Blade and none of the case studies met the inclusion criteria for follow-up time.

Randomized Controlled Trials

No RCTs were identified on transciliary fistulization for the treatment of glaucoma.

Nonrandomized Studies

Data concerning transciliary fistulization consists of case series and nonrandomized comparative studies. The nonrandomized studies have limitations including a nonrandomized design, lack of appropriate comparator groups, small sample sizes, short term follow-up, and/or significant loss of patients at follow-up.[11-13]

MINIMALLY INVASIVE MICRO SCLEROSTOMY OR TRABECULOSTOMY

Systematic Reviews

No systematic reviews were identified on minimally invasive micro sclerostomy or trabeculostomy.

Randomized Controlled Trials

No RCTs were identified on minimally invasive micro sclerostomy or trabeculostomy.

Nonrandomized Studies

The evidence is limited to two single-arm prospective trials.[14, 15] Both studies have limitations including nonrandomized design, lack of appropriate comparator groups, relatively small sample sizes, and iris clogging complications requiring additional interventions in a subset of patients. The larger study by Voskanan (2024) performed 120 minimally invasive micro sclerostomy in patients with uncontrolled glaucoma. The one-year follow-up included 93 patients and found qualified success of 82.1% (95% confidence interval [CI]: 72.9% to 89.2%) of the patients and complete success in 70.5% (60.3 to 79.4%). 60% (95% CI:49.4% to 69.9%) of the patients achieved maximum IOP level of 14 mmHg or at least 30% reduction in IOP.

IDOSE®TR (TRAVOPROST INTRACAMERAL IMPLANT)

Systematic Reviews

No systematic reviews were identified on travoprost intracameral implant.

Randomized Controlled Trials

Sarkisian (2024) published a prospective, multicenter, randomized, double-masked pivotal phase 3 trial evaluating the efficacy and safety of the travoprost intracameral slow-eluting (SE) implant (the intended commercial product) and fast-eluting (FE) implant (included primarily for masking purposes) compared to twice-daily 0.5% timolol ophthalmic solution in patients with open-angle glaucoma or ocular hypertension.[16] The primary efficacy endpoints were the mean change from baseline IOP at 8 A.M. and 10 A.M. at day 10, week 6, and month 3. Non-inferiority was achieved if the upper 95% CI on the difference in IOP change from baseline (implant minus timolol) was < 1.5 mmHg at all six timepoints and < 1 mmHg at three or more timepoints. The results showed that the SE implant was non-inferior to timolol eye drops in IOP lowering over 12 months, with a significantly greater proportion of patients in the SE implant group (83.5%) compared to the timolol group (23.9%) on fewer topical glaucoma medications at month 12 compared to screening ($p<0.0001$). Similarly, the FE implant was non-inferior to timolol over nine months, with 78.7% of patients in the FE implant group on fewer topical glaucoma medications at month 12 compared to screening ($p<0.0001$). Adverse effects were mostly mild, with treatment emergent adverse events reported in 39.5% of patients in the SE implant group, 34.0% in the FE implant group, and 20.1% in the timolol group. Study limitations include lack of long-term follow-up, the sham administration procedure for the timolol group and possible conflict of interest.

Sarkisian (2024) published the results of one of the phase three trials to evaluate the safety and IOP-lowering efficacy of two models of the travoprost intraocular implant (FE and SE).[17] The primary outcome was the mean change from baseline IOP in the study eye at 8 am and 10 am, at each of day 10, week 6, and month 3. The travoprost intraocular implant (both FE and SE types) demonstrated robust IOP reduction over the 3-month primary efficacy evaluation period after a single administration. The mean IOP reduction from baseline over the six time points ranged from 6.6 to 8.4 mmHg for the FE implant group, from 6.6 to 8.5 mmHg

for the SE implant group, and from 6.5 to 7.7 mmHg for the timolol group. The primary efficacy endpoint was met, with the upper limit of the 95% confidence interval of the difference between the implant groups and the timolol group being < 1 mmHg at all 6 time points, indicating noninferiority. Adverse events were reported in 21.5% of patients in the FE implant group, 27.2% in the SE implant group, and 10.8% in the timolol group, with the most common adverse events including iritis (FE implant, 0.5%; SE implant, 5.1%), ocular hyperemia (FE implant, 3.0%; SE implant, 2.6%), reduced visual acuity (FE implant, 1.0%; SE implant, 4.1%; timolol, 0.5%), and IOP increased (FE implant, 3.5%; SE implant, 2.6%; timolol, 2.1%). One serious eye adverse event occurred (endophthalmitis). The study's limitations include the short follow-up period of three months, use of a sham administration procedure for the timolol group and possible conflict of interest.

Bacharach (2024) published a post-hoc analysis study to compare the IOP treatment effects of the SE travoprost intracameral implant and topical prostaglandin analog (PGA) monotherapy in a subgroup subjects (n = 133) who were on prestudy PGA monotherapy prior to enrollment in two pivotal phase 3 trials.[18] The primary efficacy endpoint was the IOP-lowering treatment effect. The subjects were analyzed for the IOP treatment effects of the pre-study topical PGA monotherapy and the in-study SE travoprost intracameral implant. The SE travoprost intracameral implant demonstrated a significantly greater IOP-lowering treatment effect (-7.07 mmHg) compared to pre-study topical PGA monotherapy (-5.76 mmHg), with a superiority margin of 1.31 mmHg (95% CI: -2.01 to 0.60; p=0.0003).

PRACTICE GUIDELINE SUMMARY

American Academy of Ophthalmology (AAO)

The 2020 American Academy of Ophthalmology Preferred Practice Patterns guidelines for primary open-angle glaucoma do not discuss excimer laser trabeculostomy/trabeculotomy, femtosecond laser trabeculotomy, transciliary fistulization, minimally invasive micro sclerostomy or trabeculostomy among the various surgery options.[19] They recognize that adherence to topical eye-drops may be a barrier to optimal therapy, and notes that multiple drug delivery systems have been developed to address this issue, including Durysta®. These guidelines do not address the iDose®TR.

SUMMARY

There is not enough research to show that excimer laser trabeculostomy or trabeculotomy or femtosecond laser trabeculotomy can improve health outcomes for individuals with glaucoma. In addition, evidence-based clinical practice guidelines for glaucoma treatment do not discuss these procedures. Therefore, they are considered investigational.

There is not enough research to show that transciliary fistulization improves health outcomes for individuals with glaucoma. No clinical practice guidelines recommend transciliary fistulization for the treatment of glaucoma. Therefore, transciliary fistulization for the treatment of glaucoma is considered investigational.

There is not enough research to show that minimally invasive micro sclerostomy or trabeculostomy improve health outcomes for individuals with glaucoma. No clinical practice guidelines recommend minimally invasive micro sclerostomy or trabeculostomy for the

treatment of glaucoma. Therefore, minimally invasive micro sclerostomy or trabeculostomy for the treatment of glaucoma is considered investigational.

There is not enough research to show that travoprost drug eluting ocular implants (e.g. iDose®TR) improve health outcomes when compared to the standard of care. No clinical guidelines based on research recommend travoprost drug eluting ocular implants (e.g. iDose®TR) for the treatment of open angle glaucoma. Therefore, travoprost drug eluting ocular implants (e.g. iDose®TR) are considered investigational for treatment of open angle glaucoma.

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CODES

Codes	Number	Description
CPT	0621T	Trabeculostomy ab interno by laser
	0622T	Trabeculostomy ab interno by laser; with use of ophthalmic endoscope
	0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach
	0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug eluting implant
	0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
	1012T	Motorized ab interno trephination of sclera (sclerostomy), or trabecular meshwork (trabeculostomy), 1 or more, including injection of antifibrotic agents, when performed
	66999	Unlisted procedure, anterior segment of eye
HCPCS	J7355	Injection, travoprost, intracameral implant, 1 mcg

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