



## ***Laser Trabeculotomy and Trabeculostomy***

**Effective:** September 1, 2024

**Next Review:** May 2025

**Last Review:** July 2024

### **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, including excimer laser trabeculostomy (also known as excimer laser trabeculotomy) and femtosecond laser trabeculotomy have been proposed to improve fluid drainage from the eye to treat this disorder.

### **MEDICAL POLICY CRITERIA**

**Note:** This policy does not apply to laser trabeculoplasty.

- I. Excimer laser trabeculostomy or trabeculotomy is considered **investigational**.
- II. Femtosecond laser trabeculotomy is considered **investigational**.

*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
2. [Transciliary Fistulization for the Treatment of Glaucoma](#), Surgery, Policy No. 150

## 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.

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 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- $\mu$ m trabeculostomy openings.<sup>[1]</sup> 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.

### REGULATORY STATUS

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

## 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.<sup>[1]</sup> 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).<sup>[2]</sup> 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.<sup>[3]</sup> 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 use of glaucoma medications at 12 months. The studies of ELT included in the review were the RCT by Babighian (2010)<sup>[2]</sup> and two observational studies.<sup>[4, 5]</sup> 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 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).<sup>[6]</sup> One-year follow up data from 37 eyes showed a reduction in IOP from  $17.76 \pm 4.88$  mmHg to  $15.35 \pm 3.10$  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.<sup>[7]</sup> This included 164 eyes, 90 treated with ELT alone and 74 treated with a combination of ELT and phacoemulsification. IOP went from  $22.17 \pm 7.0$  mm Hg to  $16.84 \pm 5.2$  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.<sup>[8]</sup> 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**

Nagy (2023) published the results of a first-in-human safety study of femtosecond laser image-guided trabeculotomy in 12 patients (18 eyes).<sup>[9]</sup> At 24 months following the procedure, the mean IOP was reduced by 34.6% from  $22.3 \pm 5.5$  to  $14.5 \pm 2.6$  mmHg ( $p < 5e^{-5}$ ). No serious adverse events were reported.

## 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 ELT or FLT among the various surgery options.<sup>[10]</sup>

## SUMMARY

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

## REFERENCES

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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
	0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
HCPCS	None	

**Date of Origin:** May 2022