

Trabeculoplasty and Trabeculectomy, Laser

ACG: A-0196 (AC)
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Clinical Indications

- Laser trabeculoplasty or trabeculectomy may be indicated for **1 or more** of the following(1)(2)(3):
 - Adult open-angle glaucoma (primary or secondary) and **1 or more** of the following(3)(16)(17)(18)(19):^N
 - Need for primary surgical intervention(5)
 - Optic nerve damage continues despite reaching intraocular pressure goals.
 - Patient declines, is intolerant of, or is unable to adhere to medical therapy.(25)(26)
 - Target intraocular pressure cannot be reached medically.(27)(28)
 - Open-angle glaucoma suspect^[A] and **1 or more** of the following:^N
 - Patient declines, is intolerant of, or is unable to adhere to medical therapy.(3)
 - Target intraocular pressure cannot be reached medically.
 - Pediatric glaucoma and **1 or more** of the following^[B](29)(30)(31)(32):^N
 - Need for primary surgical intervention (ie, congenital aniridia without cataract, primary childhood glaucoma)
 - Target intraocular pressure cannot be reached medically.

Alternatives

- Alternatives include(1)(3)(36):
 - Conventional trabeculectomy
 - Pharmacotherapy(5)(9)(10)(19)

Evidence Summary

Background

Laser trabeculoplasty and trabeculectomy, like all current treatments of primary open-angle glaucoma, are aimed at reducing intraocular pressure.(2)(4)(5)(6)(7) **(EG 2)** Elevated intraocular pressure is an important risk factor for primary open-angle glaucoma and is currently the only modifiable causative factor for that disease.(4) **(EG 2)** Laser trabeculoplasty causes coagulative thermal damage to the trabecular meshwork, which lowers intraocular pressure by an unclear mechanism.(8)(9)(10) **(EG 2)** Selective laser trabeculoplasty uses a special lower-energy laser that is thought to be selectively absorbed by pigmented cells in the trabecular network, possibly

causing less thermal damage as compared with argon laser trabeculoplasty.(10)(11)(12)(13)(14) **(EG 2)** Trabeculectomy reduces intraocular pressure by providing an alternate path for aqueous fluid drainage.(2)(15) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 27 published peer reviewed articles, 1 specialty society or other evidence-based guideline, 2 Cochrane systematic reviews, and 2 book sections.

For adult open-angle glaucoma, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** An unblinded randomized controlled trial of 718 patients that included 636 eyes with open-angle glaucoma compared selective laser trabeculoplasty with medical therapy as first-line treatment and found no difference in the primary outcome of health-related quality-of-life scores; selective laser trabeculoplasty was associated with more visits at target intraocular pressure compared with medical therapy, lower rates of glaucoma disease progression, and fewer glaucoma-related ocular surgeries.(20) **(EG 1)** A secondary analysis of this trial (644 patients) found that treatment with medical therapy was associated with a more rapid progression in visual field decline compared with the patients initially treated with selective laser trabeculoplasty (26.2% vs 16.9%, respectively).(21) **(EG 2)** A 6-year follow-up study including 524 patients continued to find no difference in health-related quality-of-life scores and that selective laser trabeculoplasty was associated with more visits at or below target intraocular pressure as compared with medical therapy (70% vs 18%, respectively).(22) **(EG 1)** A systematic review and meta-analysis of 8 randomized controlled trials (including the previously described randomized controlled trial) compared 1229 open-angle glaucoma patients undergoing primary treatment by selective laser trabeculoplasty vs medications alone and found no significant difference in intraocular pressure control with selective laser trabeculoplasty compared with control achieved by medications alone; however, selective laser trabeculoplasty was associated with the use of fewer medications.(23) **(EG 1)** A systematic review concluded that, for the initial treatment of open-angle glaucoma, the clinical effectiveness of primary surgical trabeculectomy as compared with glaucoma medications is not known.(15) **(EG 1)** A systematic review of laser trabeculoplasty for the treatment of primary open-angle glaucoma concluded, based on low-certainty evidence, that patients treated with laser trabeculoplasty may have a higher risk of uncontrolled intraocular pressure at 2 years' follow-up compared with patients treated with trabeculectomy.(1) **(EG 1)** A post hoc analysis of 180 eyes with open-angle glaucoma that failed to meet goal intraocular pressure following first-line selective laser trabeculoplasty during a randomized trial (771 eyes in the original study) found, after 2 months of follow-up post-repeat laser trabeculoplasty, that intraocular pressure decreased but to a lesser degree than after the initial procedure.(24) **(EG 1)** A specialty society technology assessment states that selective laser trabeculoplasty may be used as first-line or adjunctive treatment for patients with open-angle glaucoma and that repeat trabeculoplasty may be beneficial for select patients, but that further high-quality studies are needed.(11) **(EG 2)**

For open-angle glaucoma suspect, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** An unblinded randomized controlled trial of 718 patients that included 380 eyes with ocular hypertension compared selective laser trabeculoplasty with medical therapy as first-line treatment and found no difference in the primary outcome of health-related quality-of-life scores at 36-month follow-up. Compared with medical therapy, selective laser trabeculoplasty was associated with more visits at target intraocular pressure and with modestly lower rates of progression to open-angle glaucoma for patients with ocular hypertension.(20) **(EG 1)** A follow-up study of this trial, which included 140 patients with ocular hypertension, demonstrated that patients treated with either selective laser trabeculoplasty or topical medical therapy had similar rates of progression to open-angle glaucoma and similar rates of achieving target intraocular pressure over the combined 6 years of participation.(22) **(EG 1)** A specialty society guideline states that laser trabeculoplasty may be used to treat open-angle glaucoma suspect, although medical management is considered first-line treatment.(3) **(EG 2)**

For pediatric glaucoma, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Trabeculectomy (with administration of adjunctive antimetabolites such as mitomycin C) is more likely to succeed in older, phakic pediatric glaucoma patients, and success rates of 55% to 95% have been documented. However, the procedure carries long-term risks of bleb leaks and bleb-associated endophthalmitis.(33) **(EG 2)** A retrospective review of 133 pediatric eyes with glaucoma found that a filtering surgery, such as trabeculectomy, was the initial surgery in 15% of patients.(32) **(EG 2)** A retrospective comparative study of 40 eyes in 33 patients with pediatric glaucoma showed that trabeculectomy and combined trabeculotomy-trabeculectomy, both with intraoperative mitomycin C, were equally effective at lowering intraocular pressure; the combined trabeculotomy-trabeculectomy procedure was associated with greater long-term success, as 91.3% of patients sustained a successful outcome at the last follow-up examination.(34) **(EG 2)** A specialty society technical assessment notes that pediatric glaucoma is primarily treated surgically due to ineffectiveness or intolerance of medical therapy. Trabeculectomy is one surgical option; however, antimetabolites are used during trabeculectomy due to a greater risk of scarring in children. Children also experience a higher rate of endophthalmitis.(35) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(37); 42 CFR 422.101(38)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(39); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(40); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(41)

Medicare Coverage Determinations: Medicare Coverage Database(42)

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Footnotes

[A] Open-angle glaucoma suspect is defined as the presence of ocular hypertension, suspected glaucomatous damage to the optic nerve head or retinal nerve fiber layer, or visual field changes suspicious for glaucomatous damage.(3) [A in Context Link 1]

[B] Glaucoma in children younger than 2 years can be subdivided into: (1) primary congenital glaucoma, which is the result of isolated abnormal development of the anterior chamber angle structures, and (2) secondary glaucomas, either following infantile cataract surgery or those associated with ocular or systemic syndromes. Glaucoma may also be diagnosed at any time during childhood and may include primary juvenile open-angle glaucoma and glaucoma secondary to acquired conditions, ocular anomalies, syndromes, or systemic diseases (eg, Axenfeld-Rieger syndrome, juvenile idiopathic arthritis, Peters anomaly, Sturge-Weber syndrome).(29)(30) [B in Context Link 1]

Codes

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