

Ophthalmology

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Trabeculoplasty and Trabeculectomy, Laser (MCG ORG: A-0196 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
65855	Trabeculoplasty by laser surgery, one or more sessions (defined treatment series)
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery
0730T	Trabeculotomy by laser, including optical coherence tomography guidance, when performed (emerging technology code)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding ophthalmology services, specifically laser trabeculoplasty and trabeculectomy for the surgical management of glaucoma, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of glaucoma surgery and to determine when such services are medically necessary.

Glaucoma is a leading cause of irreversible blindness and is highly prevalent in the Medicare Advantage population. When intraocular pressure cannot be controlled medically, or when a patient cannot tolerate or adhere to medical therapy, laser or incisional surgery is required to halt progressive optic nerve damage. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary glaucoma surgery and inappropriate approval of surgery performed before appropriate indications are met.

Potential Clinical Harms:

Laser trabeculoplasty and trabeculectomy: Inappropriate denial of laser trabeculoplasty or trabeculectomy for adult open-angle glaucoma when optic nerve damage continues despite medical therapy, when target intraocular pressure cannot be reached medically, or when the patient declines, cannot tolerate, or cannot adhere to medical therapy could allow continued elevation of intraocular pressure and progressive, irreversible optic nerve damage leading to permanent visual field loss and blindness. The same harm applies to qualifying open-angle glaucoma suspects and to pediatric glaucoma requiring primary surgical intervention, where delay permits ongoing optic nerve injury during a critical period.

Clinical Benefits:

Laser trabeculoplasty and trabeculectomy: MCG criteria provide validated indications drawn from a specialty society guideline, Cochrane systematic reviews, and randomized controlled trial evidence, demonstrating at least moderate certainty of at least moderate net benefit for adult open-angle glaucoma. An unblinded randomized controlled trial of 718 patients (including 636

eyes with open-angle glaucoma) supports selective laser trabeculoplasty as effective first-line and adjunctive therapy for lowering intraocular pressure. By reserving surgery for glaucoma where intraocular pressure cannot be controlled medically, optic nerve damage continues despite treatment, or the patient cannot tolerate or adhere to medical therapy, the criteria directly counter the harm of progressive optic nerve damage and irreversible blindness identified above.

Reduction of unwarranted variation and overutilization: MCG criteria also recognize pharmacotherapy and conventional trabeculectomy as alternatives, and require specific intraocular-pressure and treatment-failure findings before surgery is appropriate, reducing premature or non-indicated glaucoma surgery. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current ophthalmology specialty society guidelines and high-quality evidence. Use of these criteria ensures patients receive the most clinically appropriate level of care, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for glaucoma surgery, including laser trabeculoplasty and trabeculectomy. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications and thresholds (e.g., continued optic nerve damage despite medical therapy, inability to reach target intraocular pressure medically, or intolerance of or nonadherence to medical therapy) required to distinguish indicated from nonindicated surgery.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: For laser trabeculoplasty and trabeculectomy, no specific NCD or LCD fully establishes clinical procedural thresholds; Original Medicare criteria are not fully established for these services, requiring supplementation. Where applicable LCDs address glaucoma surgery, MCG criteria are used to supplement and do not replace them.
- Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

Within the above statutes and regulations, coverage criteria for these specific ophthalmology services are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of laser trabeculoplasty or trabeculectomy for adult open-angle glaucoma, qualifying open-angle glaucoma suspects, and pediatric glaucoma;
- The prerequisite intraocular-pressure and medical-therapy-failure findings that justify surgical intervention versus continued pharmacotherapy;
- Appropriate clinical setting and expected course for these ambulatory surgical services.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of ophthalmology services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure surgical services are not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

Trabeculoplasty and Trabeculectomy, Laser (MCG ORG: A-0196 AC)

Laser trabeculoplasty and trabeculectomy are surgical procedures used to lower intraocular pressure in glaucoma. They are indicated for adult open-angle glaucoma (primary or secondary) when there is a need for primary surgical intervention, continued optic nerve damage despite reaching intraocular pressure goals, patient decline of or intolerance to medical therapy, or inability to reach target intraocular pressure medically; for qualifying open-angle glaucoma suspects; and for pediatric glaucoma requiring primary surgical intervention or when target intraocular pressure cannot be reached medically. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

Evidence Summary

Trabeculoplasty and Trabeculectomy, Laser (MCG ORG: A-0196 AC)

The evidence for the clinical indications 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. Key evidence includes:

- For adult open-angle glaucoma, evidence demonstrates at least moderate certainty of at least moderate net benefit. An unblinded randomized controlled trial of 718 patients, including 636 eyes with open-angle glaucoma, compared selective laser trabeculoplasty with medical therapy and supports laser trabeculoplasty as effective intraocular-pressure-lowering treatment.
- Specialty society guidance and Cochrane systematic reviews support surgical intervention when optic nerve damage continues despite reaching intraocular pressure goals, when target pressure cannot be reached medically, or when the patient declines, is intolerant of, or cannot adhere to medical therapy.
- For open-angle glaucoma suspects and for pediatric glaucoma, the criteria specify the prerequisite findings (e.g., inability to reach target intraocular pressure medically, need for

primary surgical intervention in congenital aniridia without cataract or primary childhood glaucoma) under which surgery is appropriate.

Rationale (from MCG)

Use of this MCG care guideline helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate use of glaucoma surgery. The evidence-based clinical criteria assist the clinician in deciding when laser trabeculoplasty or trabeculectomy is appropriate based on intraocular-pressure control, optic nerve status, and the patient's ability to tolerate and adhere to medical therapy. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 419.22; 42 CFR 422.101
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- Medicare Coverage Determinations: Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx>

References with Citation Summary -- Trabeculoplasty and Trabeculectomy, Laser (MCG ORG: A-0196 AC, 30th Edition)

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5. Public Accessibility

Transparency Tool URL:

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To access these coverage summaries, navigate to the UM Criteria page, scroll to the bottom of the page, and click the Medical Necessity Supplementation Criteria link. All summaries are organized alphabetically by category.