

<b>Policy Name</b>	Clinical Policy – Glaucoma Surgery
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<b>Department</b>	Clinical Product & Development
<b>Subcategory</b>	Medical Management
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<b>Company Entities Supported (Select All that Apply)</b> <input checked="" type="checkbox"/> Superior Vision Benefit Management <input checked="" type="checkbox"/> Superior Vision Services <input checked="" type="checkbox"/> Superior Vision of New Jersey, Inc. <input checked="" type="checkbox"/> Block Vision of Texas, Inc. d/b/a Superior Vision of Texas <input checked="" type="checkbox"/> Davis Vision (Collectively referred to as 'Versant Health' or 'the Company')
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<b>Acronyms and Definitions</b>	
IOP	Intraocular pressure
MIGS	Minimally Invasive Glaucoma Surgery
Target Pressure	The upper limit of a range of pressures in which visual field loss is unlikely to risk a patient's vision, health or quality of life.

<b>PURPOSE</b>
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To provide the medical necessity criteria to support the indication(s) for glaucoma surgery and to render medical necessity determinations. Applicable procedure codes related to glaucoma surgery are also defined.

<b>POLICY</b>
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**A. BACKGROUND**

Glaucoma is an optic neuropathy that can lead to progressive visual field loss and significant impairment of both vision and health related quality of life. Reducing intraocular pressure is associated with a decreased risk of developing or progressing optic nerve damage. There is no absolute number or range of intraocular pressure (IOP) that defines glaucoma.<sup>1</sup>

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<sup>1</sup> Sommer, 2011

Glaucoma surgical procedures are intended to lower IOP for an extended period, thus reducing the risk of permanent optic nerve damage. IOP can be lowered in a variety of ways. One method is by enhancing the outflow of aqueous from the anterior chamber through various methods. Some types of procedures open, enhance, or stent the eye's natural drainage system usually by reducing obstruction at the level of the trabecular meshwork. A second method is to create an alternative route for aqueous drainage<sup>2</sup> through either a microshunt, fistulization of the sclera, or implantation of a glaucoma drainage implant. A third method is to reduce the amount of aqueous humor production through partial destruction of the ciliary body.<sup>3</sup>

## B. Medically Necessary

### 1. Minimally Invasive Glaucoma Surgery

- a. Select aqueous drainage assist devices with concurrent cataract extraction and implantation of an intraocular lens (66989, 66991). See Versant Health Clinical Policy 1301 Cataract Surgery for the medical necessity criteria.
- b. Select aqueous drainage assist device without concurrent cataract extraction (0167T)
  - i. Primary open angle glaucoma; and
  - ii. When a trial of medical therapy (medication and laser therapy) has been unable to control intraocular pressure and reduce the risk for further optic nerve damage due to lack of efficacy, adherence, cognitive impairment, or coexisting ocular surface disease.
- c. Excisional (Trabeculotomy, Goniotomy, GATT 65820) <sup>4,5</sup>
  - i. Initial treatment for congenital or juvenile glaucoma (does not require a trial of topical therapy), or;
  - ii. Mild to moderate open angle glaucoma; and,
  - iii. When a trial of medical therapy (medication and laser therapy) has been unable to control intraocular pressure and reduce the risk for further optic nerve damage due to lack of efficacy, adherence, cognitive impairment, or coexisting ocular surface disease.
- d. Transluminal dilation of aqueous outflow canal (66174, 66175)<sup>6</sup>
  - i. Diagnosis of mild to moderate open angle glaucoma confirmed by gonioscopy; and,
  - ii. When a trial of medical therapy (medication and laser therapy) has been unable to control intraocular pressure and reduce the risk for further optic nerve damage due to lack of efficacy, adherence, cognitive impairment, or coexisting ocular surface disease.

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<sup>2</sup> See Clinical Policy 1308 Laser Trabeculoplasty; and Clinical Policy 1322 Laser Peripheral Iridotomy.

<sup>3</sup> See Clinical Policy 1300 Cataract Surgery for procedures done in conjunction with cataract surgery

<sup>4</sup> Smith, 2022.

<sup>5</sup> Dorairaj, 2022.

<sup>6</sup> Lusthaus, 2024.

- e. Ab interno implant (Xen 0449T/0450T)<sup>7</sup>
  - i. Diagnosis of open angle glaucoma (regardless of stage)<sup>89</sup> confirmed by gonioscopy; and,
  - ii. When a trial of medical therapy (medication and laser therapy) has been unable to control intraocular pressure and reduce the risk for further optic nerve damage due to lack of efficacy, adherence, cognitive impairment, or coexisting ocular surface disease.
2. Trabeculectomy and related fistulization procedures, with or without stents or drainage device<sup>10</sup> (Ab externo implant: ExPRESS,<sup>11</sup> Ab externo XEN [66183];<sup>12</sup> Trabeculectomy [66170,66172]; Tube Shunt: Ahmed,<sup>13</sup> Baerveldt,<sup>14</sup> Molteno<sup>15</sup> [66179/66180]).
  - a. Diagnosis of glaucoma; and,
  - b. Maximum medical therapy (maximum topical therapy and if appropriate laser therapy) has been unable to control intraocular pressure and reduce the risk for further optic nerve damage due to lack of efficacy, adherence, or cognitive impairment.

### C. Not Medically Necessary

1. Glaucoma Surgery is not medically necessary as follows:
  - a. In the absence of glaucoma; or,
  - b. When tolerated medication provides adequate control of intraocular pressure; or,
  - c. When evidence of visual field loss or nerve fiber layer deficit is not documented; or,
  - d. For ocular hypertension or glaucoma suspect; or,
  - e. For off-label use of an aqueous drainage device or glaucoma drainage device; or,
  - f. When there is no risk for further optic nerve damage.
2. Glaucoma drainage devices, not explicitly approved by the FDA, are considered experimental and/or investigational and may not be considered medically necessary.

### D. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale. Documentation requires at a minimum all the following items. All items must be available upon request. For any retrospective review, a full operative report and medical plan of care are needed.

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<sup>7</sup> Panarelli, 2023.

<sup>8</sup> Grover, 2017.

<sup>9</sup> Boopathiraj, 2024.

<sup>10</sup> Minckler, 2006

<sup>11</sup> DeJong, 2011.

<sup>12</sup> Tan, 2021.

<sup>13</sup> Koo, 2015.

<sup>14</sup> Kim, 2017.

<sup>15</sup> Broadway, 2001.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be authenticated by the physician. The method used shall be handwritten or electronic signature. Stamped signatures are not acceptable.

1. Eye exam with description of medical justification for the proposed glaucoma surgical procedure and absence of contraindications for the surgery. This must include gonioscopy and thorough evaluation of the optic nerve to validate structural glaucomatous changes; and,
2. Documentation of glaucoma findings and inability to reduce risk for optic nerve damage with medical therapy due to noncompliance with medical therapy such as cost, memory problems, difficulty with instillation, adherence, or intolerance to the medication; and,
3. Documentation of ongoing risk of optic nerve damage despite topical therapies and laser trabeculoplasty, when considering trabeculectomy and related external fistulization procedures with or without stents or other drainage devices; and,
4. Allied diagnostic testing with physician's order, medical rationale, findings, interpretation and report demonstrating reproducible visual field loss with threshold perimetry, and optic disc changes on OCT and/or fundus photography. The perimetry requirement is waived for patients who cannot reliably perform this test (e.g., nystagmus); and,
5. Documentation of previously failed glaucoma surgery when applicable; and,
6. A statement from the surgeon anticipating the procedure(s) will achieve reduction of risk to the optic nerve, and that this reduction will be adequate to control the glaucoma; and,
7. An explanatory statement from the surgeon when more than one aqueous drainage assist device, or glaucoma drainage device, will be implanted in the same eye during the same operative session; and,
8. For retrospective review, detailed operative report that incorporates indications, procedure description, make, model, serial number(s) of implant(s) that are FDA approved.

## E. PROCEDURAL DETAIL

<b>CPT Codes</b>	
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure) Add on code for 0449T
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
65820	Goniotomy
66150	Fistulization of sclera for glaucoma; trephination with iridectomy
66155	Fistulization of sclera for glaucoma; thermocauterization with iridectomy
66160	Fistulization of sclera for glaucoma; sclerectomy with punch or scissors, with iridectomy

66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents)
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent
66179	Aqueous shunt to extraocular equatorial plate reservoir; external approach; without graft
66180	Aqueous shunt to extraocular equatorial plate reservoir; external approach; with graft.
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach (also known as express shunt).
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft
66250	Revision or repair of operative wound of anterior segment, any type, early or late, major or minor procedure
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., 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 (e.g., 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 with insertion of intraocular, anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more.
<b>Required Modifiers</b>	
Anatomic Modifiers	RT – Right side LT – Left side 50 – Bilateral

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<b>RELATED POLICIES AND PROCEDURES</b>	
1300	Cataract Surgery
1308	Laser Trabeculoplasty
1322	Laser Peripheral Iridotomy

<b>DOCUMENT HISTORY</b>		
<b><i>Approval Date</i></b>	<b><i>Revisions</i></b>	<b><i>Effective Date</i></b>
05/01/2018	Initial Policy	05/01/2018
03/13/2019	Annual review; no criteria change.	03/13/2019
10/18/2019	Correction of code 66160.	11/01/2019
08/19/2020	Annual review; no criteria change.	01/01/2021
07/07/2021	Annual review; added background information on IOP measurement; removed exclusion from surgery for closed angle glaucoma and excessive synechiae; removed inclusion of borderline glaucoma; added requirement for presurgical eye exam to include gonioscopy.	01/01/2022

10/06/2021	Revised criteria for surgery to not require visual field loss due to glaucoma.	01/01/2022
01/05/2022	Annual review; revised criteria for MIGS to match criteria in 1300 for same procedure codes. Remove two CMS deleted codes; add three CMS released codes.	04/01/2022
01/04/2023	Annual review; revised language related to achieving or requiring measures of target intraocular pressure to now describe risk/status of optic nerve damage as primary measurement for surgery; added goniotomy as medically necessary test for three indications; removed requirement to submit surgical clearance documentation.	07/01/2023
09/20/2023	Administrative review for CMS 2024 final rule Medicare Part C equity: no changes.	n/a
04/03/2024	Removed MIGS combination cataract surgery criteria which is retained in 1300 Cataract Surgery policy. Add indication of laser trabeculoplasty failure for trabeculotomy/goniotomy procedures; added indication of risk to the optic nerve with further laser therapy for procedures of trabeculectomy and related fistulization	07/01/2024
01/08/2025	Add criteria for iStent Infinite (drug/device historically on policy); modified criteria for XEN stent to allow use regardless of glaucoma stage.	04/01/2025

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