UTILIZATION REVIEW CRITERIA

MIGS iCare Criteria #669.20

Criteria for Microinvasive Glaucoma Surgery – CPT: 66989, 66991, 0449T, 0671T

Coverage Criteria:

Microinvasive Glaucoma Surgery (MIGS) refers to a group of surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance. MIGS procedures are categorized as internal filtration surgeries and involve minimal trauma to ocular tissues.

iCare will consider MIGS to be a medically necessary service when the device is approved/cleared by the FDA, used within accordance of the FDA indications, and when the following criteria indications are met:

For trabecular meshwork aqueous stent drainage devices approved for management of mild or moderate primary open-angle glaucoma (iStent®, iStent *inject*®, iStent *inject*® W, Hydrus®)

1. Insertion of 1 anterior segment drainage device, without an extraocular reservoir, via internal approach into the trabecular meshwork per eye; AND
2. The patient is an adult undergoing a concurrent cataract surgery*; AND
3. The patient has a diagnosis of mild or moderate primary open-angle glaucoma (POAG); AND
4. The patient is currently being treated with an ocular hypotensive medication.

(*) Cataract surgery must be performed in conjunction with the placement of trabecular meshwork aqueous stent drainage device, on the same date of service, and documented in the medical record (as outlined in the Cataract iCare Criteria #669.00).

For subconjunctival space drainage devices (XEN® 45 Gel Stent) or trabecular meshwork aqueous stent drainage devices (iStent infinite®) for management of refractory glaucoma and as a standalone procedure

1. Insertion of 1 anterior segment drainage device, without an extraocular reservoir, via internal approach into the subconjunctival space or trabecular meshwork per eye; AND
2. The patient has refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and/or mean diurnal medicated IOP greater than or equal to 20 mmHg) on maximally tolerated medical therapy (i.e., greater than or equal to 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues).

Special consideration: iStent infinite® or XEN® 45 Gel Stent may be placed as a stand-alone procedure or alongside concomitant cataract surgery. Placement in conjunction with cataract surgery must occur on the same date of service as the cataract surgery documented in the medical record (as outlined in the Cataract iCare criteria #669.00).

Note: The iStent infinite® is indicated for use in adults with primary open-angle glaucoma who have failed previous medical and surgical treatment. XEN® 45 Gel Stent is indicated for refractory glaucoma management, including cases where prior surgical treatment has failed, cases of POAG, and pigmentary or pseudoexfoliative glaucoma with open angles that have not responded to maximum tolerated medical therapy.

Contraindications:

The placement of **iStent®** is contraindicated in the presence of:

- Angle closure glaucoma (primary or secondary), including neovascular glaucoma
- Retrobulbar tumor
- Thyroid eye disease
- Sturge-Weber Syndrome
- Any condition that may cause elevated episcleral venous pressure

The placement of **iStent *inject*® and iStent *inject*® W** contraindicated in the presence of:

- Angle closure glaucoma
- Traumatic, malignant, uveitic, or neovascular glaucoma
- Discernible congenital anomalies of the anterior chamber angle
- Retrobulbar tumor
- Thyroid eye disease
- Sturge-Weber Syndrome
- Any condition that may cause elevated episcleral venous pressure

The placement of **Hydrus®** is contraindicated in the presence of:

- Angle closure glaucoma
- Traumatic, malignant, uveitic, or neovascular glaucoma
- Discernible congenital anomalies of the anterior chamber angle

The placement of **iStent infinite®** is contraindicated in the presence of:

- Angle closure glaucoma where angle has not been surgically opened
- Acute traumatic, malignant, active uveitic, or active neovascular glaucoma
- Discernible congenital anomalies of the anterior chamber angle
- Retrobulbar tumor
- Thyroid eye disease
- Sturge-Weber Syndrome
- Any condition that may cause elevated episcleral venous pressure

The placement of **XEN® 45 Gel Stent** is contraindicated in the presence of:

- Angle-closure glaucoma where angle has not been surgically opened
- Previous glaucoma shunt/valve or conjunctival scarring/pathologies in the target quadrant
- Active inflammation
- Active iris neovascularization
- Anterior chamber intraocular lens
- Intraocular silicone oil
- Vitreous in the anterior chamber

Limitations of Coverage:

Services are considered medically reasonable and necessary only when performed by appropriately trained providers. Insertion of glaucoma drainage devices herein must be performed by a qualified physician (MD or DO) who is a board certified ophthalmologist having completed a residency and/or fellowship program and who maintains ongoing certification in ophthalmology.

iCare considers the following **not** medically reasonable and necessary regarding MIGS procedures:

- Glaucoma drainage devices that do not have FDA approval/clearance.
- Glaucoma drainage devices that have been recalled.
- Use of a glaucoma drainage device outside of the FDA approval/clearance.
- Use of MIGS as a first line treatment for mild-moderate glaucoma.
- A combination of surgical MIGS procedure and aqueous shunts performed at the same time of service in the same patient.
- Phacoemulsification can be performed with a single MIGS procedure, but multiple procedures (e.g., stent and MIGS surgical procedure) cannot be performed in the same eye at the same time.
- Performing goniotomy procedure in conjunction with the insertion of a glaucoma drainage device.
- Performing trabeculectomy procedure in conjunction with the insertion of a glaucoma drainage device.
- Insertion of an anterior segment aqueous drainage device without extraocular reservoir, via internal approach into the suprachoroidal space.
- Additional insertions of anterior segment aqueous drainage device(s) without extraocular reservoir, via internal approach into the trabecular meshwork.
- Additional insertions of aqueous drainage device(s) without extraocular reservoir, via internal approach into the subconjunctival space.
- Insertion of glaucoma drainage device(s) (i.e., one or two microstents) into the trabecular meshwork is limited to one delivery system per eye when performed in conjunction with cataract surgery and when the medically reasonable and necessary criteria as stated herein are met.
    - Additional delivery system use for device insertions on one eye is considered not medically reasonable and necessary.
- Insertion of glaucoma drainage device(s) into the subconjunctival space is limited to one insertion per eye per day when the medically reasonable and necessary criteria as stated herein are met.
    - Additional device insertions are considered not medically reasonable and necessary.

Documentation Requirements:

- All documentation must be maintained in the patient's medical record and made available upon request. *The provider has a responsibility to maintain a record for possible post payment review.*
- Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date of birth and date of service[s]).
- The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- Documentation of risk, benefits, and alternatives having been explained to the patient and/or the patient's legal guardian.
- Documentation of informed consent to complete the procedure must be obtained from the patient and/or the patient's legal guardian.
- Pre-operative notes must be signed by the provider that will be performing the procedure.

CPT/ICD-10 Codes:

iStent®, iStent *inject*®, iStent *inject*® W, Hydrus®, iStent infinite®

CPT codes covered for trabecular meshwork MIGS drainage device placed with concomitant cataract surgery **(iStent®, iStent *inject*®, iStent *inject*® W, Hydrus®)** when coverage criteria are met:

66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, 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 (eg, 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 (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

ICD-10 codes covered for trabecular meshwork MIGS drainage device placed with concomitant cataract surgery **(iStent®, iStent *inject*®, iStent *inject*® W, Hydrus®)** when coverage criteria are met:

H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage

Coverage includes only 1 unit per eye per date of service for CPT code 66991 and 66989 for insertion of glaucoma drainage device(s) into the trabecular meshwork **(iStent®, iStent *inject*®, iStent *inject*® W, Hydrus®)** when performed in conjunction with cataract surgery on the date of service and when the medically reasonable and necessary criteria herein are met.

iStent infinite®

CPT codes covered for trabecular meshwork MIGS drainage device placed with concomitant cataract surgery **(iStent infinite®)** when coverage criteria are met:

66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, 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 (eg, 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 (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

ICD-10 codes covered for trabecular meshwork MIGS drainage device placed with concomitant cataract surgery **(iStent infinite®)** when coverage criteria are met:

H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage

Coverage includes only 1 unit per eye per date of service for CPT code 66991 and 66989 for insertion of glaucoma drainage device(s) into the trabecular meshwork **(iStent infinite®)** when performed in conjunction with cataract surgery on the date of service and when the medically reasonable and necessary criteria herein are met.

iStent infinite®

CPT code covered for trabecular meshwork MIGS drainage device placed *without* concomitant cataract surgery **(iStent infinite®)** when coverage criteria are met:

0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

ICD-10 codes covered for trabecular meshwork MIGS drainage device placed *without* concomitant cataract surgery **(iStent infinite®)** when coverage criteria are met:

H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage

Coverage includes only 1 unit per eye per date of service for CPT code 0671T for insertion of glaucoma drainage device(s) into the trabecular meshwork **(iStent infinite®)** when the medically reasonable and necessary criteria herein are met.

XEN® 45 Gel Stent

CPT code covered for subconjunctival space MIGS drainage device **(XEN® 45 Gel Stent)** when coverage criteria are met:

0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device

Note: CPT Code 0450T for additional device insertion is not covered

ICD-10 codes covered for subconjunctival space MIGS drainage device **(XEN® 45 Gel Stent)** when coverage criteria are met:

H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1114	Primary open-angle glaucoma, right eye, indeterminate stage
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1124	Primary open-angle glaucoma, left eye, indeterminate stage
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1134	Primary open-angle glaucoma, bilateral, indeterminate stage
H40.1211	Low-tension glaucoma, right eye, mild stage
H40.1212	Low-tension glaucoma, right eye, moderate stage
H40.1213	Low-tension glaucoma, right eye, severe stage
H40.1214	Low-tension glaucoma, right eye, indeterminate stage
H40.1221	Low-tension glaucoma, left eye, mild stage
H40.1222	Low-tension glaucoma, left eye, moderate stage
H40.1223	Low-tension glaucoma, left eye, severe stage
H40.1224	Low-tension glaucoma, left eye, indeterminate stage
H40.1231	Low-tension glaucoma, bilateral, mild stage
H40.1232	Low-tension glaucoma, bilateral, moderate stage
H40.1233	Low-tension glaucoma, bilateral, severe stage
H40.1234	Low-tension glaucoma, bilateral, indeterminate stage
H40.1311	Pigmentary glaucoma, right eye, mild stage
H40.1312	Pigmentary glaucoma, right eye, moderate stage
H40.1313	Pigmentary glaucoma, right eye, severe stage
H40.1314	Pigmentary glaucoma, right eye, indeterminate stage
H40.1321	Pigmentary glaucoma, left eye, mild stage
H40.1322	Pigmentary glaucoma, left eye, moderate stage
H40.1323	Pigmentary glaucoma, left eye, severe stage
H40.1324	Pigmentary glaucoma, left eye, indeterminate stage
H40.1331	Pigmentary glaucoma, bilateral, mild stage
H40.1332	Pigmentary glaucoma, bilateral, moderate stage
H40.1333	Pigmentary glaucoma, bilateral, severe stage
H40.1334	Pigmentary glaucoma, bilateral, indeterminate stage
H40.1411	Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412	Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1413	Capsular glaucoma with pseudoexfoliation of lens, right eye, severe stage
H40.1414	Capsular glaucoma with pseudoexfoliation of lens, right eye, indeterminate stage
H40.1421	Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422	Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage
H40.1423	Capsular glaucoma with pseudoexfoliation of lens, left eye, severe stage
H40.1424	Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage
H40.1431	Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432	Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage
H40.1433	Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434	Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage

Coverage includes only 1 unit per eye per date of service for CPT code 0449T for insertion of glaucoma drainage device(s) into the subconjunctival space **(XEN® 45 Gel Stent)** when the medically reasonable and necessary criteria herein are met.

Definition and Background:

Primary open-angle glaucoma (POAG) is a chronic, progressive optic neuropathy, involving a characteristic acquired atrophy of the optic nerve and loss of retinal ganglion cells and their axons. Increased intraocular pressure (IOP) due to a buildup of aqueous fluid within the eye is a risk factor of POAG and can lead to visual field loss and optic nerve damage, usually without any associated pain or discomfort. The increased IOP is secondary to an imbalance between aqueous fluid secretion and fluid outflow despite an open angle.

Reduction of the IOP to slow the development of optic nerve damage is a goal in POAG management. IOP can be reduced by medical treatment or surgery, alone or in combination. Surgical care is considered the next treatment option when the maximum tolerated medical therapy fails to control progression of glaucomatous optic neuropathy.

Traditional glaucoma surgeries, such as trabeculectomy, or tube shunt surgeries with aqueous drainage implants, lower IOP by improving outflow of the eye fluid. These procedures are performed from outside the eye, or an ab externo approach. The term MIGS refers to a group of newer surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance. MIGS procedures involve minimal trauma to ocular tissues, and when compared with traditional filtration surgery, MIGS may promise faster recovery time and less severe complications.

Sources:

Portions of the criteria herein may have been adopted in whole or in part from Local Coverage Determinations as provided by the applicable fiscal intermediary and/or criteria from certain health plan partners.

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REVIEW AND REVISION HISTORY		
Date	**Description**	**Approver & Title**
November 22, 2024	Approval by PAC	Approved by PAC via email vote
November 4, 2024	Final draft presented to iCare's Professional Advisory Committee (PAC) for review	Dr. Amanda Lee, VP of UM Dr. Smith Blanc, Director of UM