iStent infinite Good Documentation Practices & Peri-Operative Documentation for Medical Necessity

This resource packet is intended to assist providers in documenting medical necessity for iStent infinite® Trabecular Micro-Bypass System Model iS3, first standalone trabecular micro-bypass device to reduce elevated intraocular pressure (IOP) in patients with primary open-angle glaucoma uncontrolled by prior medical and surgical therapy**.**

REIMBURSEMENT DISCLAIMER

Glaukos provides this billing and coding information for educational purposes only. This guide is not affirmative instruction as to which codes, modifiers, or documentation to use for a particular service, supply, procedure, or treatment, nor is it exhaustive. It is the provider's responsibility to determine and submit the appropriate codes, modifiers, and documentation for any service, supply, procedure, or treatment rendered. Actual codes, modifiers, and documentation is at the sole discretion of the treating provider and/or facility. Contact your local payer for specific coding and coverage guidelines. Glaukos cannot guarantee medical benefit coverage or reimbursement with the codes listed or directions provided in this guide. Information included in this material was obtained from third-party sources and is accurate as of the time of its publication but is subject to change without notice.

INDICATION

The iStent infinite® Trabecular Micro-Bypass System Model iS3 is an implantable device intended to reduce the intraocular pressure (IOP) of the eye. It is indicated for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

The iStent infinite® is contraindicated in eyes with angle-closure glaucoma where the angle has not been surgically opened, acute traumatic, malignant, active uveitic, or active neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure.

Please see additional Important Safety Information on last page and Directions for Use (DFU) for a complete list of contraindications, warnings, precautions, and adverse events (AEs).

DEFINING MEDICAL NECESSITY

Medicare and other third-party insurance payers provide coverage and payment of services and items used in treatment based on what is considered medically necessary and reasonable. Medicare.gov defines medical necessity as "services or supplies that are needed to diagnose or treat your medical condition and that meet accepted standards of medical practice."[1]

[1] https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html

Upon receipt of a claim for services provided, Medicare and other payers may request additional documentation to prove the medical necessity of treatment provided. The documentation to support treatment should include:

- a history of the patient's condition,
- testing used to diagnosis the illness or injury,
- all current and previous medical and surgical interventions used to treat the condition,
- failure of current and previous medical and surgical interventions, and
- a treatment plan and expected outcomes.

Failure to comply with a payer's request for additional medical records, or records that do not demonstrate medical necessity, will likely result in non-coverage of the claim.

PRACTICE DOCUMENTATION & RESOURCES IMPORTANT TO PAYERS

To aid in supporting medical necessity for iStent infinite® this guide includes a sample operative note which may be used to support medical necessity for reasonable care. Additional documents may also support the medical documentation and claim for the beneficiary. These recommendations are for informational purposes only and must be tailored to your own practice and the patient's clinical condition.

- Sample Language for Pre-Determination/Authorization, Requests for Medical Necessity, or Claim Additional Documentation Request (ADR), Appeal and/or Denial Template Letter
- Chart Documentation Checklist, as provided by the payer correspondence
- Medical Records | Rationale to support medical necessity
    - H&P
    - Pre-operative consultation report
    - Operative Report
    - Discharge/Expected Outcomes/Follow Up

ISTENT INFINITE SAMPLE OPERATIVE NOTE

Operative notes should clearly identify the patient, the date of surgery, the surgeon and assistant, the preoperative and postoperative diagnoses, the procedure(s) performed and on which eye, the implantable device used, the anesthesia and other pharmacotherapeutics used, and whether there were any intraoperative complications. In addition, the notes should include a summary of the patient's glaucoma staging, including prior medications and failed surgical treatments.

Below is a brief example of operative notes for a standalone procedure using iStent infinite®. Practitioners should use their medical judgment and training to customize this sample to best reflect the patient treated and procedure(s) performed.

Date of Surgery	
Patient Name	
Surgeon	
Assistant	
Preoperative Diagnosis	
Postoperative Diagnosis	
Procedure(s) Performed	
Device(s) Implanted	
Anesthesia	
Intraoperative Complications	
Proposed target IOP (e.g., <20mmHg)	

Indications for Surgery: *The patient had a history of open angle glaucoma and has failed prior medical and surgical intervention. Additionally, report Visual Field Abnormality VF mean defect score, Optic Nerve cup to disc ratio, as well as stage of glaucoma (ICD-10) (mild, moderate, severe).*

Include detail regarding current medications, including previous medical and surgical therapy (laser and incisional) [Include further detail about the medical and surgical treatments that have failed.]

Procedure: *The patient was brought to the preoperative area and received topical anesthesia, then was brought to the operating room, prepped, and draped in the usual sterile ophthalmic manner. The operative eye was identified.*

A lid speculum was placed. The operating microscope was placed in the proper position for ideal viewing. A clear corneal incision was made temporally. Miostat was instilled and viscoelastic was injected into the anterior chamber of the eye. The eye was examined and using a gonioscopy prism, the angle was visualized and was open with the trabecular meshwork identified.

The conjunctiva was marked for iStent infinite® placement 2 clock hours apart for a total of 3 marks in the nasal angle. The first and second devices were implanted without complication and there was immediate blood reflux from Schlemm's canal into the anterior chamber through the stents. The injector handpiece was removed from the eye. The scope was adjusted and surgeons positioning was adjusted to allow for the proper angle for injector entry into the anterior chamber. The patient's head was rotated to allow the best view upon visualizing the nasal angle with the goniolens. The superonasal angle examined, then additional viscoelastic was instilled and the third stent was then positioned with the injector in the trabecular meshwork. There was some blood reflux present. All 3 stents were visualized in the proper anatomical position.

Viscoelastic and residual blood were removed from the eye with irrigation. BSS was injected into the corneal incisions for hydration, and they were confirmed to be sealed with a Weck-cel sponge with a well-formed anterior chamber and a reasonable intraocular pressure determined by palpation. The patient received [postoperative medication regimen]. The patient left the operating room in satisfactory condition with no complications noted.

For additional information and support, please contact marketaccess@glaukos.com.