

2024

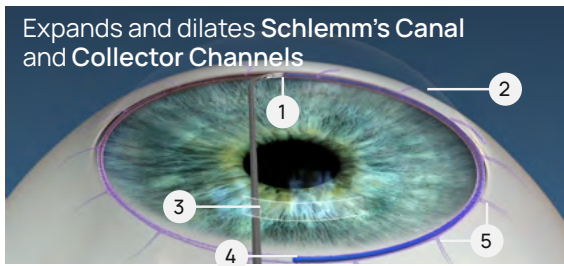
OMNI[®] Surgical System Reimbursement Guide

About OMNI

A comprehensive outflow procedure enabled by the OMNI Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.¹

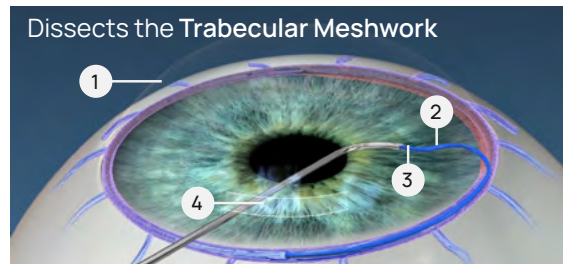
Surgeons use OMNI to perform minimally invasive, implant-free glaucoma procedures.

- Used in both standalone and combo cataract minimally invasive glaucoma surgery (MIGS)
- Target three points of resistance intended to lower intraocular pressure (IOP)²
- Sustained long-term IOP reduction³



- 1 Cannula Tip
- 2 Schlemm's Canal
- 3 Clear Corneal Microincision
- 4 Microcatheter
- 5 Collector Channels

&



- 1 Trabecular Meshwork
- 2 Microcatheter
- 3 Cannula Tip
- 4 Clear Corneal Microincision

Coding Resources

Providers are responsible for selecting the code that most closely represents the procedure performed. The correct code will be based on the medical record documentation, the operative report, as well as payor coding guidelines and public coding guidance.

Source	Coding Guidance
2024 AMA CPT ^{4,5} Codebook Guidelines	Do not report CPT 66174 in conjunction with CPT 65820.
AMA CPT Assistant ^{6,7,8}	Report CPT 66174 when both procedures are performed together as the incision in goniotomy is incidental to CPT 66174.
AAO Executives ⁹	Report either CPT 66174 or 65820, but not both codes when transluminal dilation (e.g., canaloplasty) is performed for at least 3 clock hours and the trabecular meshwork is opened (e.g., goniotomy) for at least 3 clock hours.
Corcoran ¹⁰	Report only CPT 66174. CPT 65820 is bundled with CPT 66174.
CMS NCCI Edits ¹¹	CMS established a claim edit prohibiting separate payment of CPT 65820 with CPT 66174. If both codes are submitted, only 66174 will be paid.

NOTE: Sight Sciences does not provide coding guidance. Follow AMA CPT Codebook guidelines, AMA CPT Assistant, NCCI edits, and Society Coding Fact Sheets for appropriate coding guidance.

2024 Medicare Payment Rates

Rates listed are national unadjusted allowable amounts and not a guarantee of payment.

CPT Code	Descriptor	HOPD ¹²	ASC ¹³	Physician ¹⁴
65820	Goniotomy	\$3,878	\$2,045	\$804
66174	Canaloplasty	\$3,878	\$2,045	\$608
66982	Complex cataract	\$2,223	\$1,184	\$724
66984	Routine cataract	\$2,223	\$1,184	\$528

NOTE: The payment information listed does not guarantee coverage or payment. Actual payment may vary by location. Commercial and Medicare Advantage plans may be based on contractual agreements or negotiated fees between the physician and the payor. Questions regarding your contracted payment rates should be directed to your payor's provider representative.

HCPCS Device C-Codes

Medicare requires that hospital outpatient departments report C1889 on the claim. While this C-code does not trigger additional Medicare facility payment, it is reported to establish future Ambulatory Payment Classification (APC) rates.

Code Type	Code	Code Description
HCPCS	C1889	Implantable/insertable device, not otherwise classified
Revenue	278	Other Implants

HCPCS C-Codes are tracking codes established by the Centers for Medicare & Medicaid Services (CMS) to assist Medicare in establishing future APC payment rates. They only apply to Medicare hospital outpatient claims and do not trigger additional Medicare payment to the facility. For device-intensive procedures like the OMNI Surgical System, when performed in the hospital outpatient setting, Medicare requires the reporting of a device-related HCPCS Level II code on the claim. This is necessary to help ensure appropriate costs are captured for use in setting future hospital outpatient APC payment levels. ASCs billing with CMS-1500 forms are not required to report C-codes.

Compliant Device Reporting

To maintain compliance, hospitals should report appropriate C-Code (C1889) with appropriate CPT Code. Claims data has shown that very few hospitals are appropriately reporting implantable or insertable device costs when used. For example, CPT 66174 has a cost associated with the procedure to identify the use of a device such as the OMNI Surgical System.

- C-Codes are used by the Centers of Medicare & Medicaid Services (CMS) to track and determine future APC payment rates.
- C-Codes pertain to only Medicare hospital outpatient claims.
- C-codes are critical when CMS determines changes to outpatient hospital payment rates.
- When using an OMNI Surgical System Surgical Instrument use **Revenue code 0278** with **HCPCS code C1889**.

Revenue Code	Description	HCPCS Code	Service Date	Units	Total Charges
0360	Canaloplasty	66174	XX/XX/XX	1	XXXXXX
0278	Other medical/surgical supplies	C1889	XX/XX/XX	1	XXXXXX

Revenue code 0278 is used to report insertable/implantable devices (e.g., OMNI)

HCPCS code C1889 is used to report insertable/implantable devices (e.g., OMNI) that do not have a more specific HCPCS code

Use to accurately report device costs. Set an appropriate charge based on the hospital's usual methodology that includes the cost of the device such as OMNI

Common ICD-10-CM Diagnosis Coding

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes are used to report patient diagnoses and health conditions for visits/services in all healthcare settings. Providers should consult the ICD-10-CM code set, payor coverage policies or other payor guidelines when determining the appropriate diagnosis code(s) to submit to health plans. Coding is a clinical decision and providers should accurately code to the highest level of specificity.

ICD-10-CM ¹⁵	Description	ICD-10-CM ¹⁵	Description
H40.1110	Primary open-angle glaucoma, right eye, stage unspecified	H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1111	Primary open-angle glaucoma, right eye, mild stage	H40.1124	Primary open-angle glaucoma, left eye, indeterminate stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage	H40.1130	Primary open-angle glaucoma, bilateral, stage unspecified
H40.1113	Primary open-angle glaucoma, right eye, severe stage	H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1114	Primary open-angle glaucoma, right eye, indeterminate stage	H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1120	Primary open-angle glaucoma, left eye, stage unspecified	H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1121	Primary open-angle glaucoma, left eye, mild stage	H40.1134	Primary open-angle glaucoma, bilateral, indeterminate stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage		

Common Modifiers

Modifier ¹⁶	Description	Definition ¹⁶
-RT	Right side	Indicates procedure was performed on the right eye
-LT	Left side	Indicates procedure was performed on the left eye
-50	Bilateral procedure	Indicates procedure was performed on both eyes that day
-51	Multiple procedures	Indicates procedure was performed with other procedures that day
-54	Surgical care only	Indicates surgical portion of the procedure
-55	Postoperative management only	Indicates the postoperative management portion of the procedure
-73	Discontinued HOPD/ASC	Discontinued procedure prior to administration of anesthesia
-74	Discontinued HOPD/ASC	Discontinued procedure after the administration of anesthesia
-79	Unrelated procedure	Unrelated procedure or service by the same physician during the postoperative period

Co-Management of Ophthalmic Surgery Postoperative Care

In clinically appropriate situations, an operating ophthalmologist and patient may determine that a co-management arrangement is medically appropriate based on the patient's individual circumstances or needs. Any delegation of a surgeon's postoperative responsibilities to another non-operating practitioner and any payments to either party should be completely transparent to the patient and only done after obtaining the patient's informed consent in writing. A co-management arrangement is a relationship between an operating ophthalmologist and a non-operating practitioner where they have shared responsibilities for a patient's postoperative care (e.g., patient request, unavailability of the operating ophthalmologist, patient's inability or unwillingness to return to the operating ophthalmologist, changes in follow-up plans). The operating ophthalmologist is ultimately responsible for the care of the patient, from the initial determination of the need for surgery through completion of postoperative care and medical stability of the patient.¹⁷

Before entering into a co-management arrangement ensure to:

- Consult legal counsel before entering into any co-management or referral arrangement to ensure it complies with all applicable state and federal laws.*
- Confirm payor policies and reimbursement for co-management arrangements with a particular payor.
- Obtain patient's informed consent to the co-management arrangement in writing. Retain a copy of the informed consent in the patient's medical record.
- Complete a written co-management agreement outlining the specific co-management protocols for the patient. Retain a copy in the patient's medical record.
- Understand that the operating ophthalmologist determines whether/if transfer of postoperative care is clinically appropriate and is responsible to discuss potential co-management arrangements with the patient.
- Be aware that it is the responsibility of the operating ophthalmologist to identify a qualified provider to which they would delegate the postoperative care of their patient.
- Cite appropriate co-management modifiers on both providers' claim forms.
- Confirm that both providers ensure completeness and accuracy of claim forms, including date of surgery, date that postoperative care is relinquished/assumed, and number of postoperative

* For example, make sure the co-management arrangement complies with federal Stark law and the Anti-kickback Statue (as well as any state laws) concerning fee splitting and patient brokering.

NOTE: Providers are responsible for reviewing their scope of practice, as determined by statutes, state legislatures, state medical boards, and other entities when considering co-management of canaloplasty and other procedures. Please reference state legislatures and rules adopted by the appropriate licensing entity.

2024 OMNI Coverage Summary

Medicare Coverage:

- The OMNI procedure is eligible for Medicare coverage when used as a standalone procedure or in combination with cataract surgery.
- Check with your carrier to confirm medical necessity and coverage details prior to the procedure.
- Note that Medicare coverage for CPT 66174 is outside of a formal national coverage determination (NCD) or a local coverage determination (LCD). Providers are to follow Medicare guidelines on medical necessity, which includes the following:
 - Treatment is appropriate for individual patient based on approved label.
 - Treatment is within accepted standards of medical practice for the patient's condition.







Commercial, Medicare Advantage, Medicaid Coverage:

- Coverage varies by each individual patient and their specific coverage benefits.
- Prior to treatment, it is important to check patient benefits, current medical policy, and contracts to minimize reimbursement challenges.
- There is no guarantee of coverage.
- A prior authorization or pre-determination is recommended prior to the procedure.

Coverage Overview

Commercial and Medicare Advantage Payors

Before the procedure, check payor policies and medical necessity criteria to determine benefits and coverage. Prior authorization is recommended.

Insurance	Favorable Commercial Coverage	Favorable Medicare Advantage Coverage
	<ul style="list-style-type: none"> ✓ Yes, standalone canaloplasty ✓ Yes, canaloplasty plus cataracts 	<ul style="list-style-type: none"> ✓ Yes, confirm benefits and medical necessity with your Medicare contractor.
	<ul style="list-style-type: none"> ✓ Yes, standalone canaloplasty ✗ Note: OMNI in combination with cataract removal is not a covered procedure currently. Seek approval on a case-by-case through the authorization process. 	<ul style="list-style-type: none"> ✓ Yes, standalone canaloplasty is covered. Confirm benefits and medical necessity with your Medicare contractor. ✗ Note: For OMNI in combination with cataract removal, confirm coverage and medical necessity criteria with your Medicare contractor. Seek approval on a case-by-case through the authorization process.
	<ul style="list-style-type: none"> ✓ Yes, standalone canaloplasty ✓ Yes, canaloplasty plus cataracts 	<ul style="list-style-type: none"> ✓ Yes, confirm benefits and medical necessity with your Medicare contractor.
	<ul style="list-style-type: none"> ✓ Yes, standalone canaloplasty ✓ Yes, canaloplasty plus cataracts 	<ul style="list-style-type: none"> ✓ Yes, confirm benefits and medical necessity with your Medicare contractor.
	<ul style="list-style-type: none"> ✓ Yes, standalone OMNI ✓ Yes, OMNI plus cataracts 	<ul style="list-style-type: none"> ✓ Yes, confirm benefits and medical necessity with your Medicare contractor.
	<ul style="list-style-type: none"> ✗ For standalone goniotomy or standalone canaloplasty (or in combination with cataract removal), the procedure is not covered. Seek approval on a case-by-case through the authorization process. 	<ul style="list-style-type: none"> ✗ For standalone canaloplasty or OMNI in combination with cataract removal, seek approval on a case-by-case through the authorization or appeal process.

*The majority of BCBS plans cover canaloplasty. Check with the specific plan for coverage and medical necessity.

Frequently Asked Questions

Do commercial payors require prior authorization for OMNI?

If so, what information is required?

Performing a benefit verification prior to treatment may provide insight into prior authorization criteria.

Please consider:

- Including a payor-specific prior authorization form with your request, if required.
- Checking the payor's medical policy (if available) to understand coverage criteria including documentation and chart notes that list any previous medical and surgical history.
- Outlining treatments along with outcomes, patient-specific treatment goals or comorbidities, and target IOPs for patient.
- Including a letter of medical necessity describing the patient's condition (contact your Market Access Team for more information or sample templates).

Frequently Asked Questions (cont.)

When do I report HCPCS C1889 (implantable/insertable device, not otherwise specified)?

For Medicare cases in the hospital outpatient setting, CMS requires the reporting of C1889 under revenue code 278. Check your ASC payor contracts to determine the appropriate billing.

Is OMNI used to perform viscocanalostomy?

No, viscocanalostomy is a different procedure entirely from canaloplasty. OMNI is FDA indicated for canaloplasty followed by trabeculotomy. It is not indicated to perform a viscocanalostomy. Any reference to OMNI as a viscocanalostomy device is incorrect.

May gonioscopy (92020) be billed with the claim for the surgery?

No. Gonioscopy is required during surgery to insert the OMNI instrument and is an incidental part of the service. CPT instructs that a code designated as a "separate procedure", such as gonioscopy, should not be reported in addition to the code for the total procedure of which it is considered an integral component.

Notes

¹ U.S. Food & Drug Administration (FDA) 510(k)-Premarket Notification cleared Instructions for Use [Traditional 510(k) K202678] <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202678>

² Trabecular meshwork (trabeculotomy), Schlemm's canal (canaloplasty), and collector channels (canaloplasty).

³ Williamson BK, Vold SD, Campbell A, Hirsch L, Selvadurai D, Aminlari AE, Cotliar J, Dickerson JE. Canaloplasty and Trabeculotomy with the OMNI System in Patients with Open-Angle Glaucoma: Two-Year Results from the ROMEO Study. *Clin Ophthalmol*. 2023 Apr 6;17:1057-1066. doi: 10.2147/OPTH.S407918. PMID: 37056792; PMCID: PMC10086214. <https://pubmed.ncbi.nlm.nih.gov/37056792/>

⁴ CPT codes, descriptions, and other data only are copyright 2023 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein

⁵ 2024 CPT Professional Edition, page 507, parenthetical notation

⁶ Surgery: Eye and Ocular Adnexa. Frequently Asked Questions. September 2019 page 10. AMA CPT Assistant. Retrieved on 01/26/24 from <https://www.findacode.com/newsletters/ama-cpt-assistant/index.php?i=16564&hl=66174>

⁷ Surgery: Eye and Ocular Adnexa (Q&A) (December 2018, page 9). AMA CPT Assistant. Retrieved on 01/26/24 from <https://www.findacode.com/newsletters/ama-cpt-assistant/index.php?i=16170&hl=66174>.

⁸ Coding Brief: Reporting Goniotomy With Other Glaucoma Surgery. (2022, May). AMA CPT Assistant. Retrieved on 01/26/24 from <https://www.findacode.com/newsletters/ama-cpt-assistant/coding-brief-reporting-goniotomy-with-other-glaucoma-surgery-may-2022-5-17047.html>

⁹ The American Academy of Ophthalmic (AAO) Executives Fact Sheet: Goniotomy (as of January 12, 2023). <https://www.aao.org/Assets/c1c5ad6a-f611-4c41-988c-991514f68602/637896975656770000/goniotomy-fs-pdf?inline=1>

¹⁰ Corcoran and Corcoran: OMNI is reported with CPT 66174. https://corcoranccg.com/wp-content/uploads/securepdfs/FAQ_OMNI-Sight-Sciences_010122.pdf

¹¹ CMS NCCI Procedure to Procedure Edit File as of 01/26/24. <https://www.cms.gov/medicare/coding-billing/ncci-medicare>

¹² CMS-1786-FC. Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment Period (NFRM). 2024. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems. <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc>

¹³ CMS-1786-FC. Ambulatory Surgical Center Payment- Notice of Final Rulemaking with Comment Period (NFRM). 2024. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems. <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1786-fc>

¹⁴ CMS-1784-F. 2024. Final Rule. Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2024. <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f>

¹⁵ About ICD-10-CM: <https://www.cdc.gov/nchs/icd/icd-10-cm/index.html>

¹⁶ AAPC. What are medical coding modifiers? <https://www.aapc.com/modifiers/>. Accessed January 3, 2023

¹⁷ AAO 2016 Position Paper titled, Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care". <https://www.aao.org/education/ethics-detail/guidelines-comanagement-postoperative-care>



sightsciences.com

MARKET ACCESS

Reimbursement support is available to help answer coverage, coding, and payment questions.

email:

sightaccess@sightsciences.com

SIGHT ACCESS PARTNERS

Sight Access includes a field-based team that provides reimbursement support.

SIGHT ACCESS RESOURCES

Contact our team to access our library of resources to support your practice and increase access for your patients.

DISCLAIMER

This document is designed for illustrative use only. Coverage policies vary and are subject to change. There is no guarantee of coverage. Sight Sciences provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for the care provided. Sight Sciences makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payors as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage, and payment policies. This document aids with FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

OMNI is FDA indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.