2025 TearScience[™] Billing & Coding Guide

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Billing and coding guides

The information provided in this guide is general information only and is not legal advice nor is it advice about how to code, complete, or submit any claim for payment for health care services or goods.

The information provided represents no statement, promise, or guarantee by Johnson & Johnson Surgical Vision, Inc. concerning levels of reimbursement, payment or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Johnson & Johnson Surgical Vision, Inc. that these codes will be appropriate or that reimbursement will be made.

It is not intended to increase or maximize reimbursement by any payer.

The information provided here provides only an overview of Johnson & Johnson Surgical Vision, Inc.'s understanding of current reimbursement policies and may not provide all the information necessary to understand a particular situation. It is the responsibility of the health care provider, such as a hospital or a physician, to submit complete, accurate and appropriate bills or claims for payment that comply with applicable laws and regulations and third-party payer requirements, and to determine the appropriate codes, charges, and modifiers that the provider uses for those purposes. Third-party payers may have policies and coding requirements that differ from those described here, and such policies can change over time.

Johnson & Johnson Surgical Vision, Inc. disclaims any responsibility for claims submitted by health care physicians or others. Physicians should check and verify current policies and requirements with the payer.

For additional questions or information contact:

Johnson & Johnson TearScience[™] Reimbursement Hotline T: 1-855-877-3462 • F: 1-855-631-4335 • jjsvhema@its.jnj.com

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Abbreviations

| ABN | Advance Beneficiary Notice of Non-coverage | LT | Left |
|---------------|---|------|--|
| AMA | American Medical Association | MGD | Meibomian Gland Dysfunction |
| CMS | Centers for Medicare & Medicaid Services | MGE | Meibomian Gland Evaluator |
| CPT® | Current Procedural Terminology | OSI | Ocular Surface Interferometer |
| DMI | Dynamic Meibomian Imager | NEHB | Notice of Exclusion from Health Plan Benefits |
| HCPCS | Healthcare Common Procedure Coding System | RT | Right |
| ICD- 10-CM | International Classification of Disease, 10 th revision – Clinical Modification | | |
| | | | |

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TearScience[®] Billing & Coding

Introduction to TearScience[™] Billing and Coding

This billing guide provides a general overview of the current coverage, coding, and payment landscape for the following Johnson & Johnson Surgical Vision products used in the imaging and evaluation of meibomian glands and treatment of Meibomian Gland Dysfunction (MGD):

LipiScan[™] Dynamic Meibomian Imager (DMI) LipiFlow[™] Thermal Pulsation System LipiView[™] II Ocular Surface Interferometer (OSI)

Meibomian Gland Evaluator (MGE)

Coverage

- The 21st Century Cures Act¹ amended the language regarding Category III CPT[®] code coverage:
 - Category III codes can no longer have blanket non-coverage for the class, and coverage must either be determined at the claim level or by written policy for the specific code in question.
- There are **no published coverage policies** for the Johnson & Johnson TearScience[™] portfolio of products.
- Private insurers often follow the lead of Medicare coverage and policies but are also guided by their own policies which are subject to change from time to time and may change based on insurer.
 - For any questions about a specific payer's coverage policy, it is advisable to contact them directly.
- Where products and treatments are not covered, an Advanced Beneficiary Notice of Non-coverage (ABN)² or other financial waiver may be necessary to ensure that the patient accepts financial responsibility.

TearScience[™] Billing & Coding

Coding & billing

- When billing CPT[®] codes, the American Medical Association (AMA) advises that providers
 select codes that most accurately identify the procedure or service that was performed,
 rather than those that merely approximate the service provided if a more specific code is available.³
- There could be a contracted fee schedule for a product or service, regardless of the payer's coverage stance.

Payment

- Non-covered items are usually the financial responsibility of the patient; providers are encouraged to contact the patient's plan and confirm the payer's rules prior to treating the patient.
 - The patient should be notified prior to treatment about the anticipated out-of-pocket expense if a claim is denied.
 - If payment is collected from the patient and the claim is paid by the payer, the patient should be refunded.
- For Medicare patients, there is no implied non-coverage for the TearScience[™] portfolio of products; however, since no coverage determination exists, and claims may be denied, it is advisable to obtain a financial waiver from the patient ahead of time.
- Some commercial and Medicare Advantage plans may have contract requirements for participating network providers to request a pre-certification review prior to administering treatment to the patient.
 - If the payer confirms the treatment is a non-covered service, treatment can only be administered after the patient signs and understands a financial waiver and any other documents required by the payer.
 - If these requirements are not met, the payer might deny the claim and restrict the provider from holding the patient responsible for the charges.

Applicable codes

Payers may have specific requirements for claims filing, especially for participating, in-network providers. This information is usually found in the provider handbook/manual, or you can call the payer's Provider Relations department. It is highly recommended that you verify the payer's requirements for claims filing, to prevent your office from violating any contractual obligations that you may have.

Diagnostic codes

The following are common diagnostic ICD-10-CM codes⁴ associated with dry eye disease and MGD. Please note that this is not an exhaustive list. It is the provider's responsibility to use the ICD-10-CM diagnostic code that most accurately describes the patient's condition.

| Description | Diagnostic Code | |
|-----------------------------------|-----------------|--|
| Dry Eye Syndrome | | |
| Right lacrimal gland | H04.121 | |
| Left lacrimal gland | H04.122 | |
| Bilateral lacrimal glands | H04.123 | |
| Meibomian Gland Dysfunction (MGD) | | |
| Right Eye | | |
| Upper eyelid | H02.881 | |
| Lower eyelid | H02.882 | |
| Lower and upper eyelids | H02.88A | |
| Unspecified right eyelid | H02.883 | |
| Left Eye | | |
| Upper eyelid | H02.884 | |
| Lower eyelid | H02.885 | |
| Lower and upper eyelids | H02.88B | |
| Unspecified left eyelid | H02.886 | |
| Unspecified Eye | | |
| Unspecified eye or eyelid | H02.889 | |

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Applicable codes

Category III CPT[®] codes³

| CPT [®] Code | Description | |
|-----------------------|--|--|
| LipiScan™ | | |
| 0507T | Near-infrared dual imaging (i.e., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report | |
| LipiFlow [™] | | |
| 0207T | Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral | |
| LipiView™ | | |
| 0330T | Tear film imaging, unilateral or bilateral, with interpretation and report | |
| 0507T | Near-infrared dual imaging (i.e., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report | |
| Meibomian G | aland Evaluator (MGE) ^a | |
| 67999 | Unlisted procedure, eyelids | |
| 92499 | Unlisted ophthalmological service or procedure | |

^a The included codes are CPT[®] codes payers may recognize for meibomian gland evaluation, which is considered an incidental part of biomicroscopy.

It is important to note that 0207T is a unilateral code; **if a bilateral procedure is performed, it is appropriate to bill for two units or two claim lines using the RT and LT modifiers**. Please see below for more information on these modifiers.

Modifier codes for sides

In some instances, procedure codes do not indicate on which side of the body a procedure is performed. In those situations, the modifier RT (right) or LT (left) is used to indicate this. When billing a unilateral code bilaterally, the code should be billed twice, once for each side of the body on which the procedure is performed, including using each modifier below once per line.

| Modifier | Description | Comments |
|----------|------------------------|---|
| -RT | Right side of the body | Use this code in conjunction with 0207T when billing for the ${f LipiFlow}^{ m m}$ procedure |
| -LT | Left side of the body | Use this code in conjunction with 0207T when billing for the LipiFlow [™] procedure |

Financial waivers & forms

Financial waivers

A financial waiver can take several forms, depending on the insurance type or company. Many payers, including traditional Medicare, require you to use a standardized, approved format. Others will accept a generic format.

- Medicare Part B: an Advance Beneficiary Notice of Non-coverage (ABN)² is required for services where coverage is ambiguous or doubtful and may be useful where a service is never covered. The fee may be collected from the patient at the time of service or after a Medicare denial of the claim.
 - When submitting a claim to Medicare, providers may use the modifier -GX or -GY to report that an executed ABN is on file for a service that is expected to be non-covered.
- Medicare Advantage (Part C Medicare): a pre-determination of benefits is often required to identify the financial responsibility of the beneficiary prior to performing non-covered services. Medicare Advantage plans may have their own financial waiver forms; clinicians should contact the Plans to obtain the appropriate form.
- Non-Medicare (e.g., commercial) insurance: a Notice of Exclusion from Health Plan Benefits (NEHB)⁵ is used in place of an ABN.

| Modifier | Description | Comments |
|----------|---|--|
| -GA | Waiver of Liability Statement Issued as Required by Payer Policy, Individual Case | Use this modifier to report when you issue a mandatory ABN for a service as required and it is on file. You do not need to submit a copy of the ABN, but you must have it available upon request |
| -GX | Notice of Liability Issued, Voluntary Under Payer Policy | Use this modifier to report when you issue a voluntary ABN for a service that a payer never covers because it is statutorily excluded or is not an allowed payer benefit |
| -GY | Item or Service Statutorily Excluded, Does Not Meet the Definition of Any | Use this modifier to report that payer statutorily excludes the item or service, or the item or service does not meet the definition of any payer benefit. |
| -GZ | Item or Service Expected to Be Denied as Not Reasonable and Necessary | Use this modifier to report when you expect the payer to deny payment of the item or service due to a lack of medical necessity and no ABN was issued |

Modifier codes

Forms

Below are links where forms can be obtained. It is the responsibility of the clinician and their offices to determine the appropriate form for the situation. The respective websites contain instructions for filling out the forms.

- Centers for Medicare & Medicaid Services (CMS) ABN form: <u>https://www.cms.gov/Medicare/</u> <u>Medicare-General-Information/BNI/ABN</u>
- Other applicable forms: <u>https://www.corcoranccg.com/products/forms/</u>

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References

- 1. US government (2016) Public Law 114–255, 130 STAT. 1033. To Accelerate the Discovery, Development, and Delivery of 21st Century Cures, and for Other Purposes. Available from: https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf.
- 2. Centers for Medicare and Medicaid Services (2021) FFS ABN. Available from: <u>https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN</u>.
- 3. American Medical Association (2019) CPT 2020 Professional Edition.
- 4. AAPC (2020) ICD-10 CM Expert: Diagnosis Codes for Providers & Facilities.
- 5. Corcoran Consulting Group (2022). Forms. Available from: <u>https://www.corcoranccg.com/products/forms/</u>.

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A. Notifier:

B. Patient Name:

Advance Beneficiary Notice of Non-coverage (ABN)

<u>NOTE:</u> If Medicare doesn't pay for D._____below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D**.______below.

| D. | E. Reason Medicare May Not Pay: | F. Estimated Cost |
|----|---------------------------------|-------------------|
| | | |
| | | |
| | | |

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D**._____listed above.
- **Note:** If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

OPTION 1. I want the D.______ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
 OPTION 2. I want the D.______ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.
 OPTION 3. I don't want the D.______ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You may ask to receive a copy.

| I. Signature: | J. Date: |
|---------------|----------|
| | |

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (Exp.01/31/2026)

NOTICE OF EXCLUSION FROM HEALTH PLAN BENEFITS

You need to make a choice about the assessment and treatment of your ocular surface disease using:

Tear film imaging

Dual imaging of glands

Meibomian gland evaluation

LipiFlow[®] treatment

Please note that when you receive services that are not a covered benefit, you are responsible to pay for them. The purpose of this notice is to help you make an informed choice about whether or not you want to receive these services knowing that you will have to pay for them yourself. Before you make a decision about your options, you should read this entire notice carefully. *Ask us to explain if you don't understand why your health care*

service plan may not pay.

Your doctor has recommended certain tests to assess vour ocular surface disease and to determine if meibomian gland dysfunction (MGD) is a contributory factor. The intent is to determine how to treat your condition and whether LipiFlow® will help. A number of options exist including: lid scrubs, artificial tears, antibiotics, antiinflammatory agents, and ophthalmic surgery. Testing is not medically necessary; it is Treatment with LipiFlow[®] is also optional. The major difference between optional. testing with tear film and gland imaging, and treatment of MGD with LipiFlow[®] is the degree of remediation of the causes and symptoms of ocular surface disease; it's probably greater with assessment and treatment of your ocular surface disease as recommended by your doctor.

You are responsible for all of the fees associated with non-covered services. The total charge for these services is \$_____.

Beneficiary Agreement

Accordingly, the undersigned accepts full financial responsibility for the non-covered services described above.

Signature of patient or person acting on patient's behalf

Date

Relationship to patient (if signing on patient's behalf)