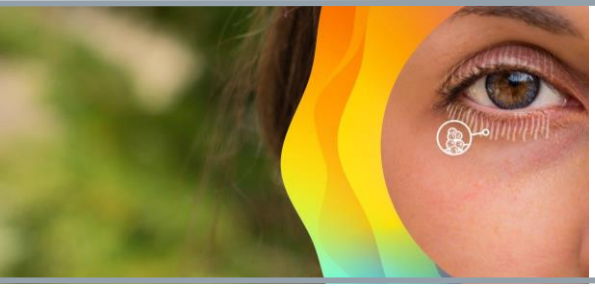

TearScience®

2024 Billing & Coding Guide

Focus on Exceptional Outcomes

At **Johnson & Johnson Vision**, we have a bold ambition: to change the trajectory of eye health worldwide. Through our operating companies, we deliver innovation that enables eye care professionals to create better outcomes for patients throughout their lives, with products and technologies that address unmet needs including refractive error, cataracts, and dry eye.

Billing and Coding Guide

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 and Johnson TearScience® Reimbursement Hotline
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F: 1-855-631-4335
TearScience@PriaHealthcare.com

Table of Content & Abbreviations

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List of Abbreviations

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

TearScience® Billing and 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 assessment 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 Act[1] 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.

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 codes[4] 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

Applicable Codes

Category III CPT® codes[3]

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 Gland 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 **LipiFlow®** 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 Codes

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.

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: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN
- Other applicable forms: https://www.corcoranccg.com/products/forms/

References

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: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.
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: https://www.corcoranccg.com/products/forms/.

A. Notifier:

B. Patient Name: **C. Identification Number:**

Advance Beneficiary Notice of Non-coverage (ABN)

NOTE: 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 also receive a copy.

I. Signature:	J. Date:

CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: AltFormatRequest@cms.hhs.gov.

Patient's Name: MRN:

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 your 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, anti-inflammatory agents, and ophthalmic surgery. Testing is not medically necessary; it is optional. Treatment with LipiFlow® is also optional. The major difference between 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)