ILUVIEN®
(fluocinolone acetonide intravitreal implant) 0.19mg

Billing and Coding Guide

A guide for healthcare providers (HCPs) who administer ILUVIEN in hospital outpatient departments (HOPDs), ambulatory surgery centers (ASCs), or physicians' offices for Diabetic Macular Edema (DME) and Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the eye (chronic NIU-PS).

ANI Pharmaceuticals, Inc., developed this guide to assist HCPs in understanding coding and billing that may be appropriate when submitting a claim for ILUVIEN. Specifically, it addresses instances where the product is purchased and administered by an HCP and billed to a patient's medical health insurance plan.

Disclaimer

Please note the information in this guide is intended for informational purposes only and does not guarantee coverage or reimbursement or provide legal advice. This resource is not intended to increase or maximize reimbursement by any payer. While ANI has attempted to be current as of the issue date of this guide, the information may not reflect current policies. **It is the HCP's responsibility to confirm coverage, coding, and billing requirements with the patient's individual payer.** Coding and coverage policies are subject to change.

INDICATIONS

ILUVIEN is a corticosteroid indicated for:

- the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.
- the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- ILUVIEN is contraindicated in patients with glaucoma who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

Please see additional Important Safety Information throughout.

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Coding overview

This section outlines codes to consider when an HCP purchases ILUVIEN, administers it to a patient in an HOPD, ASC, or physician office, and submits a claim for ILUVIEN and the intravitreal implantation.

Coding for ILUVIEN

Healthcare Common Procedure Coding System (HCPCS)

The following product-specific HCPCS code may be used to report ILUVIEN. A product specific HCPCS code does not guarantee reimbursement and may not apply to all public or private payers. Check with the payer for specific prior authorization, coding, or claims requirements.

HCPCS Code[1]	Description	Appropriate use
J7313	Injection, fluocinolone acetonide, intravitreal implant (Iluvien), 0.01 mg	1 billing unit is equal to 0.01 mg of ILUVIEN. A 0.19 mg implant may be reported with 19 billing units

HCPCS modifiers

Modifiers provide payers with additional information regarding the services rendered. The following modifiers may be applicable to ILUVIEN. Check with the payer for specific coverage, coding and billing requirements for services rendered.

Modifier[1]	Description	Appropriate use
JZ	Zero drug amount discarded/not administered to any patient	Report modifier JZ with J7313 to show that there was no drug wastage (Required for Medicare claims; check other payer policies)
TB	Drug or biological acquired with the 340B program pricing discount, reported for informational purposes	Report modifier TB with J7313 when ILUVIEN is acquired through the 340B Drug Discount program (Required for Medicare claims)

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

- **Intravitreal Injection-related Effects:** Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. For patients with non-infectious uveitis affecting the posterior segment, hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection. Patients may experience temporary blurred vision after injection of the implant.
- **Intraocular Pressure (IOP) Increase:** Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be routinely monitored during the course of the treatment.

National Drug Code (NDC)[2,3]

Payers may require HCPs to report an NDC on medical claims in addition to an appropriate HCPCS code. In compliance with the Health Insurance Portability and Accountability Act (HIPAA), HCPs should add a leading zero to report the NDC in an 11-digit format. See the appropriate placement of the leading zero below to convert to the correct 11-digit NDC:

10-digit NDC	11-digit NDC	Appropriate use
68611-190-02	68611-0190-02	Single-dose, intravitreal implant that contains 0.19 mg of ILUVIEN

The NDC is typically preceded with NDC qualifier "N4": N468611019002. When required by payers, report "UN" as the unit of measure (UoM) and NDC quantity of "1":

N468611019002 UN1

Payer requirements for NDC and UoM reporting on the claim vary by payer and policy; verify reporting requirements with the payer.

Intravitreal implantation

Current Procedural Terminology (CPT) codes identify specific medical procedures performed by a physician or other qualified HCP. The following code may be used to report the intravitreal injection of ILUVIEN by a healthcare provider:

CPT Code[4]	Description	Appropriate use
67027	Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous	Check payer policy for administration reporting requirements
67028	Intravitreal injection of a pharmacologic agent (separate procedure)	

CPT modifiers may be used to communicate more information to the payer. The following CPT modifiers may be applicable to ILUVIEN:

CPT Modifier[1,4]	Description	Appropriate use
LT	Left side	LT or RT may be added to the CPT code to identify which eye ILUVIEN was administered in
RT	Right side	
52	Reduced services	The use of modifier 52 indicates a portion of the procedure as described was not performed at the discretion of the physician (eg, no removal of the vitreous)

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

- **Cataracts:** The use of corticosteroids may result in posterior subcapsular cataract formation.
- **Delayed Corneal Wound Healing:** The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.

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Revenue codes

HOPDs use revenue codes to report specific accommodations and/or ancillary charges. Hospitals use them to identify the department that provided services, the type of services performed, and the supplies used. Revenue codes vary by payer.

Service	Revenue code[5,a]	Description
ILUVIEN	0636	Drugs requiring detailed coding
Intravitreal administration	0361	Operating room services, minor surgery

[a]Other revenue codes may apply.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

- **Corneal and Scleral Melting:** Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of ophthalmic corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation of the globe.
- **Bacterial Infections:** Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.
- **Viral Infections:** Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.
- **Fungal Infections:** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.
- **Risk of Implant Migration:** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

Diabetic Macular Edema

Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of ILUVIEN for diabetic macular edema include: cataract (82%), myodesopsia (21%), eye pain (15%), conjunctival hemorrhage (13%), posterior capsule opacification (9%), eye irritation (8%), vitreous detachment (7%), conjunctivitis (4%), corneal oedema (4%), foreign body sensation in eyes (3%), eye pruritus (3%), ocular hyperaemia (3%), optic atrophy (2%), ocular discomfort (2%), photophobia (2%), retinal exudates (2%), anterior chamber cell (2%), and eye discharge (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: anemia (11%), headache (9%), renal failure (9%), and pneumonia (7%)

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 34% of ILUVIEN patients versus 10% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 20% of ILUVIEN patients versus 4% of sham patients. 38% of the patients who received ILUVIEN were subsequently treated with IOP-lowering medications during the study versus 14% of sham patients. 5% of the patients who received ILUVIEN needed surgical intervention for elevated IOP versus 1% of sham patients

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Diagnosis coding for ILUVIEN

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes are used to report the patient-specific diagnosis documented in the medical record. Report ICD-10-CM codes to the highest level of specificity. The following codes may be reported to support the medical necessity of ILUVIEN:

Diabetic macular edema (DME)			
	ICD-10-CM[6]		
Description	Right Eye	Left Eye	Bilateral
Diabetes mellitus due to underlying condition with...			
Mild nonproliferative diabetic retinopathy with macular edema	E08.3211	E08.3212	E08.3213
Moderate nonproliferative diabetic retinopathy with macular edema	E08.3311	E08.3312	E08.3313
Severe nonproliferative diabetic retinopathy with macular edema	E08.3411	E08.3412	E08.3413
Proliferative diabetic retinopathy with macular edema	E08.3511	E08.3512	E08.3513
Drug or chemical induced diabetes mellitus with...			
Mild nonproliferative diabetic retinopathy with macular edema	E09.3211	E09.3212	E09.3213
Moderate nonproliferative diabetic retinopathy with macular edema	E09.3311	E09.3312	E09.3313
Severe nonproliferative diabetic retinopathy with macular edema	E09.3411	E09.3412	E09.3413
Proliferative diabetic retinopathy with macular edema	E09.3511	E09.3512	E09.3513
Type 1 diabetes mellitus with...			
Mild nonproliferative diabetic retinopathy with macular edema	E10.3211	E10.3212	E10.3213
Moderate nonproliferative diabetic retinopathy with macular edema	E10.3311	E10.3312	E10.3313
Severe nonproliferative diabetic retinopathy with macular edema	E10.3411	E10.3412	E10.3413
Proliferative diabetic retinopathy with macular edema	E10.3511	E10.3512	E10.3513
Type 2 diabetes mellitus with...			
Mild nonproliferative diabetic retinopathy with macular edema	E11.3211	E11.3212	E11.3213
Moderate nonproliferative diabetic retinopathy with macular edema	E11.3311	E11.3312	E11.3313
Severe nonproliferative diabetic retinopathy with macular edema	E11.3411	E11.3412	E11.3413
Proliferative diabetic retinopathy with macular edema	E11.3511	E11.3512	E11.3513
Other specified diabetes mellitus with...			
Mild nonproliferative diabetic retinopathy with macular edema	E13.3211	E13.3212	E13.3213
Moderate nonproliferative diabetic retinopathy with macular edema	E13.3311	E13.3312	E13.3313
Severe nonproliferative diabetic retinopathy with macular edema	E13.3411	E13.3412	E13.3413
Proliferative diabetic retinopathy with macular edem	E13.3511	E13.3512	E13.3513

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS (cont)

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN group (82%) compared with sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN group and 19 months in the sham group. Among these patients, 80% of ILUVIEN subjects versus 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 months (median month 15 for both ILUVIEN group and for sham) of the studies.

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Diagnosis coding for ILUVIEN (cont.)

Chronic non-infectious uveitis affecting the posterior segment of the eye (chronic NIU-PS)				
	ICD-10-CM[6]			
Description	Right Eye	Left Eye	Bilateral	Unspecified
Intermediate uveitis				
Posterior cyclitis	H30.21	H30.22	H30.23	H30.20
Panuveitis				
Panuveitis	H44.111	H44.112	H44.113	H44.119
Posterior uveitis				
Unspecified focal chorioretinal inflammation (choroiditis/chorioretinitis - NOS)	H30.001	H30.002	H30.003	H30.009
Focal chorioretinal inflammation, juxtapapillary	H30.011	H30.012	H30.013	H30.019
Focal chorioretinal inflammation of posterior pole	H30.021	H30.022	H30.023	H30.029
Focal chorioretinal inflammation, peripheral	H30.031	H30.032	H30.033	H30.039
Focal chorioretinal inflammation, macular or paramacular	H30.041	H30.042	H30.043	H30.049
Unspecified disseminated chorioretinal inflammation (choroiretinitis/choroiditis)	H30.101	H30.102	H30.103	H30.109
Disseminated chorioretinal inflammation (choroiditis/chorioretinitis), posterior pole	H30.111	H30.112	H30.113	H30.119
Disseminated chorioretinal inflammation (choroiditis/chorioretinitis), peripheral	H30.121	H30.122	H30.123	H30.129
Disseminated chorioretinal inflammation, generalized	H30.131	H30.132	H30.133	H30.139
Unspecified chorioretinal inflammation	H30.91	H30.92	H30.93	H30.90
Other chorioretinal inflammation	H30.891	H30.892	H30.893	H30.899
Harada disease	H30.811	H30.812	H30.813	H30.819
Vogt-Koyanagi syndrome	H20.821	H20.822	H20.823	H20.829
Acute posterior multifocal placoid pigment epitheliopathy	H30.141	H30.142	H30.143	H30.149

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS (cont)

Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

Ocular adverse reactions reported by greater than or equal to 1% of patients in the three combined clinical trials through 12 months following injection of fluocinolone acetonide intravitreal implant: cataract (56%), visual acuity reduced (15%), macular edema (11%), uveitis (10%), conjunctival hemorrhage (8%), eye pain (8%), hypotony of eye (7%), anterior chamber inflammation (5%), dry eye (4%), vitreous opacities (4%), conjunctivitis (4%), posterior capsule opacification (4%), ocular hyperemia (4%), vitreous haze (3%), foreign body sensation in eyes (3%), vitritis (3%), vitreous floaters (3%), eye pruritus (3%), conjunctival hyperemia (2%), ocular discomfort (2%), macular fibrosis (2%), glaucoma (2%), photopsia (2%), vitreous hemorrhage (2%), iridocyclitis (1%), eye inflammation (1%), choroiditis (1%), eye irritation (1%), visual field defect (1%), and lacrimation increased (1%). Non-ocular adverse reactions reported by greater than or equal to 2% of patients include: nasopharyngitis (5%), hypertension (3%), and arthralgia (2%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 22% of fluocinolone acetonide patients versus 12% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 12% of fluocinolone acetonide patients versus 3% of sham patients. 43% of the patients who received fluocinolone acetonide were subsequently treated with IOP-lowering medications during the study versus 41% of sham patients. 2% of the patients who received fluocinolone acetonide needed surgical intervention for elevated IOP versus 2% of sham patients.

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Sample claim form: CMS-1500 (837P)[7]

Use of the codes and information provided on this sample claim form does not guarantee reimbursement. HCPs are solely responsible for determining the appropriate codes and for any action taken in billing. Please consult with the applicable payer to understand the payer's specific billing requirements, including guidance for electronic claims.

The following is a sample CMS-1500 claim form for the intravitreal injection of ILUVIEN 0.19 mg in the left eye.

Item Number 21 Diagnosis

Enter the appropriate ICD-10-CM diagnosis code

Final code depends on medical record documentation

Item Number 24A Date(s) of Service

The "N4" qualifier is required before the NDC; do not include dashes.

Some payers may also require the UoM and quantity

N468611019002 UN1

Check payer requirements and format for reporting NDC and UoM

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

	24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	N468611019002 UN1 MM DD YY	MM DD YY	11		J7313	JZ	A		19		NPI	
2	MM DD YY	MM DD YY	11		67027	LT	A		1		NPI	
3											NPI	
4											NPI	
5											NPI	
6											NPI	

PHYSICIAN OR SUPPLIER INFORMATION

Item Number 24D Procedures/Services/Supplies

Enter the appropriate CPT/HCPCS codes and Modifiers, eg,

- **Drug:** J7313 for ILUVIEN
- **Modifier:** JZ to show that no product was wasted
- **Administration:** 67027 for intravitreal implantation
- **Modifier:** LT to indicate the implantation occurred in the left eye

Add additional modifiers as appropriate

Item Number 24E Diagnosis Pointer

Enter the letter (A-L) that corresponds to the diagnosis in Item 21

Item Number 24G Units

Enter the appropriate number of billing units for each line item.

- 1 billing unit = 0.01 mg of ILUVIEN

Sample claim form: CMS-1450/UB-04 (837I)[8]

Use of the codes and information provided on this sample claim form does not guarantee reimbursement. HCPs are solely responsible for determining the appropriate codes and for any action taken in billing. Please consult with the applicable payer to understand the payer's specific billing requirements, including guidance for electronic claims submission.

The following sample CMS-1450 (UB-04) claim form is for the intravitreal injection of ILUVIEN 0.19 mg in the left eye.

FL 42 Revenue Code

Enter the appropriate revenue code, eg,

- 0636 for ILUVIEN
- 0361 for intravitreal implantation

Other revenue codes may apply

FL 43 Revenue Description

The "N4" qualifier is required before the NDC; do not include dashes.

Some payers may also require the UoM and quantity

N468611019002 UN1

Check payer requirements and format for reporting NDC and UoM

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0636	N468611019002 UN1 ILUVIEN	J7313 JZ	MM DD YY	19	XXX XX		
2	0361	intravitreal implantation	67027 LT	MM DD YY	1	XXX XX		
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23		PAGE ____ OF ____	CREATION DATE		TOTALS			

FL 44 HCPCS

Enter the appropriate CPT/HCPCS codes and modifiers, eg,

- **Drug:** J7313 for ILUVIEN
- **Modifier:** JZ to show that no product was wasted
- **Administration:** 67027 for intravitreal implantation
- **Modifier:** LT to indicate the implantation occurred in the left eye

Add additional modifiers as appropriate

FL 46 Units of Service

Enter the appropriate number of billing units for each line item.

- 1 billing unit = 0.01 mg of ILUVIEN

50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
						57 OTHER PRV ID

58 INS	NSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.

63 TR	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

66 DX	67 I	A J	B K	C L	D M	E N	F O	G P	H Q	68

FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes

Enter the appropriate ICD-10-CM diagnosis code

Final code depends on medical record documentation

ILUVIEN®
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access plus
Reimbursement and Patient Assistance

Support for Your Patients

The AccessPlus Program is dedicated to helping patients get access to ILUVIEN, including help with

- **Benefits investigation**
- **Reimbursement support**
- **Financial assistance**
- **Product acquisition**

References:

1. Centers for Medicare & Medicaid Services. April 2025 alpha-numeric HCPCS file. Accessed April 15, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
2. ILUVIEN. Prescribing Information. Alimera Sciences, Inc.
3. Centers for Medicare & Medicaid Services. MCPM chapter 26 – completing and processing form CMS-1500 data set. Accessed April 15, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf
4. American Medical Association. CPT 2025 Professional Edition. AMA; 2024. All rights reserved. CPT® is a registered trademark of the American Medical Association.
5. Noridian Healthcare Solutions. Revenue codes. Accessed April 15, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes
6. Centers for Medicare & Medicaid Services. 2025 ICD-10-CM. Accessed April 15, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes#
7. Novitas Solutions. Part B MAC (JH). EDI: paper to electronic claim crosswalk (5010) CMS-1500. Updated February 11, 2025. Accessed April 15, 2025. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00004769
8. Novitas Solutions. Part A MAC (JH). EDI: paper to electronic claim crosswalk (5010) CMS-1450. Updated January 27, 2025. Accessed April 15, 2025. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00004768

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