

Iluvien® (fluocinonide acetonide implant)

(Intravitreal)

Document Number: IC-0246

Last Review Date: 09/01/2022 Date of Origin: 03/31/2015

Dates Reviewed: 03/2015, 04/2016, 10/2016, 04/2017, 04/2018, 05/2019, 05/2020, 09/2021, 09/2022

I. Length of Authorization

Coverage will be provided for 1 implant per eye every 36 months and may be renewed.

II. Dosing Limits

- A. Quantity Limit (max daily dose) [NDC Unit]:
 - Iluvien 0.19 mg intravitreal implant: 2 implants every 36 months
- B. Max Units (per dose and over time) [HCPCS Unit]:
 - 38 billable units every 36 months

(Quantity Limits/Max units are based on administration to BOTH eyes)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Universal Criteria 1

- Patient is free of ocular and periocular infections; AND
- Patient has not received any of the following sustained-release intravitreal corticosteroids:
 - o Dexamethasone within the prior 4 months (i.e., Ozurdex®)
 - o Triamcinolone acetonide within the prior 12 weeks (i.e., Xipere®)
 - Fluocinolone acetonide within the prior 30 months (i.e., Retisert®) or 36 months
 (i.e., Yutiq®); AND
- Patient does not have glaucoma with a cup to disk ratio greater than 0.8; AND
- Patient does not have a torn or ruptured posterior lens capsule; AND
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND



Patient's intraocular pressure is measured at baseline and periodically throughout therapy;
 AND

Diabetic Macular Edema (DME) †

- Patient is at least 18 years of age; AND
- Patient has been previously treated with a course of corticosteroids; AND
- Patient did not have a clinically significant rise in intraocular pressure from prior corticosteroid treatment

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); ♠ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; AND
- Disease response as indicated by stabilization of visual acuity or improvement in bestcorrected visual acuity (BCVA) score when compared to baseline; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis and retinal detachments, increase in intraocular pressure, eye inflammation, posterior subcapsular cataracts, glaucoma, etc.

V. Dosage/Administration

Indication	Dose
Macular Edema	Administer 0.19 mg fluocinolone acetonide intravitreal implant into the affected eye(s), in a non-bioerodable intravitreal implant drug delivery system, once every 36 months.

VI. Billing Code/Availability Information

HCPCS Code:

• J7313 – Injection, fluocinolone acetonide, intravitreal implant (iluvien), 0.01 mg; 1 billable unit = 0.01 mg

NDC:

• Iluvien 0.19 mg intravitreal implant: 68611-0190-xx

VII. References

1. Iluvien [package insert]. Alpharetta, GA; Alimera Sciences, Inc; November 2016. Accessed July 2022.



- 2. Schmidt-Erfurth U, Garcia-Arumi J, Bandello F, et al. Guidelines for the Management of Diabetic Macular Edema by the European Society of Retina Specialists (EURETINA). Ophthalmologica. 2017;237(4):185-222.
- 3. Wong TY, Sun J, Kawasaki R, et al. Guidelines on Diabetic Eye Care. The International Council of Ophthalmology Recommendations for Screening, Follow-up, Referral, and Treatment Based on Resource Settings. Ophthalmology 2018;125:1608-1622
- 4. Cunha-Vaz J, Ashton P, Iezzi R, et al. Sustained delivery fluocinolone acetonide vitreous implants: long-term benefit in patients with chronic diabetic macular edema. Ophthalmology. 2014;121(10):1892. Epub 2014 Jun 14.
- 5. Palmetto GBA. Local Coverage Article: Billing and Coding: FDA approves Iluvien for Diabetic Macular Edema (A54750). Centers for Medicare & Medicaid Services, Inc. Updated on 10/28/2019 with effective date 11/07/2019. Accessed July 2022.

Appendix 1 – Covered Diagnosis Codes

ICD-10	Description	
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema	
E08.3211	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye	
E08.3212	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye	
E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral	
E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E08.3311	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye	
E08.3312	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye	
E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	
E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E08.3411	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye	
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye	
E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral	



ICD-10	Description	
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye	
E08.3512	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye	
E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral	
E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye	
E08.37X1	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, right eye	
E08.37X2	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, left eye	
E08.37X3	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, bilateral	
E08.37X9	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, unspecified eye	
E09.311	Drug- or chemical-induced diabetes mellitus with unspecified diabetic retinopathy with macular edema	
E09.3211	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	
E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	



ICD-10	Description	
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	
E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	
E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E09.3511	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	
E09.3512	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	
E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	
E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	
E09.37X1	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	
E09.37X2	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	
E09.37X3	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	
E09.37X9	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	



ICD-10	Description		
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye		
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye		
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral		
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye		
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye		
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye		
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral		
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye		
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye		
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye		
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral		
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye		
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema		
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye		
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye		
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral		
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye		
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye		
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye		
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral		
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye		
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye		



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ICD-10	Description	
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema	
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	



ICD-10	Description	
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	
E13.37X1	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	
E13.37X2	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	
E13.37X9	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): M	NCD/LCD/LCA Document(s): A54750	
https://www.cms.gov/medicare-coverage-database/new-search/search-		
results.aspx?keyword=a54750&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CT		
A%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP		

Medicare Part B Administrative Contractor (MAC) Jurisdictions			
Jurisdiction	Applicable State/US Territory	Contractor	
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC	



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	Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor	
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC	
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)	
6	MN, WI, IL	National Government Services, Inc. (NGS)	
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.	
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)	
N (9)	FL, PR, VI	First Coast Service Options, Inc.	
J (10)	TN, GA, AL	Palmetto GBA, LLC	
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC	
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.	
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)	
15	KY, OH	CGS Administrators, LLC	



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Minneapolis, MN 55459-0052
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Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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1.800.940.5049 (TTY: 763.847.4013).
ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049
(መስጣት ለተሳናቸው: 763.847.4013 ).
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- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。
ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).
ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ
1.800.940.5049 (TTY: 763.847.4013).
ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049
(መስጣት ለተሳናቸው: 763.847.4013 ).
ဟ်သူ၌ဟ်သး– နမ့်ကတိ၊ ကညီ ကျို်အယိ, နှမၤန္ဈ် ကျို်အတါမၤစၤၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သုန္ဦလီ၊ ကိႏ 1.800.940.5049 (TTY: 763.847.4013).
ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY:
ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។
         ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).
ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).
주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1,800,940,5049 (TTY: 763,847,4013), 번으로 전화해 주십시오.
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PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa

1.800.940.5049 (TTY: 763.847.4013).