

# Local Coverage Article: Billing and Coding: FDA approves Iluvien for Diabetic Macular Edema (A54750)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

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## Article Information

### General Information

**Article ID**

A54750

**Original Effective Date**

12/30/2015

**Article Title**

Billing and Coding: FDA approves Iluvien for Diabetic  
Macular Edema

**Revision Effective Date**

11/07/2019

**Article Type**

Billing and Coding

**Revision Ending Date**

N/A

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Statement**

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**Retirement Date**

N/A

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## **CMS National Coverage Policy**

N/A

## **Article Guidance**

### **Article Text:**

On September 26, 2014, The US Food and Drug Administration approved ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg 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. ILUVIEN® is an intravitreal implant of fluocinolone acetonide and is the first DME treatment to deliver 36 months of continuous, low-dose corticosteroid with a single injection. The ILUVIEN® intravitreal implant is designed to release fluocinolone acetonide/day at an initial rate of 0.25 µg/day.

### **To submit a Part B claim:**

- Submit HCPCS code J7313 (fluocinolone acetonide intravitreal implant,0.19 mg )
- Total Dosage 0.19 mg, placed in narrative field
- One of the ICD-10 diagnoses below.

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## **Coding Information**

<b>CPT/HCPCS Codes</b>
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**Group 1 Paragraph:**

CPT/HCPCS Codes

**Group 1 Codes:**

CODE	DESCRIPTION
67028	INTRAVITREAL INJECTION OF A PHARMACOLOGIC AGENT (SEPARATE PROCEDURE)
J7313	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT (ILUVIEN), 0.01 MG

**CPT/HCPCS Modifiers**

N/A

**ICD-10 Codes that Support Medical Necessity****Group 1 Paragraph:**

Covered ICD-10 Codes

**Group 1 Codes:**

ICD-10 CODE	DESCRIPTION
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
E10.3311	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
E10.3411	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

ICD-10 CODE	DESCRIPTION
	macular edema, bilateral
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
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
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
E11.3311	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
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
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
E11.3511	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,

ICD-10 CODE	DESCRIPTION
	bilateral

**ICD-10 Codes that DO NOT Support Medical Necessity**

N/A

**Additional ICD-10 Information**

N/A

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**Other Coding Information**

N/A

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
11/07/2019	R6	Under <b>CPT/HCPCS Codes Group 1: Codes</b> the description was changed for HCPCS code J7313. This revision is due to 4 <sup>th</sup> quarter CPT®/HCPCS Code update and becomes effective on 10/1/2019.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/03/2019	R5	This article is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs and incorporate into related Billing and Coding Articles.
02/26/2018	R4	The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. Effective 02/26/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.
10/01/2016	R3	Annual review with no revisions made.
10/01/2016	R2	Under <b>ICD-10 Codes That Support Medical Necessity</b> added ICD-10 codes E10.3211, E10.3212, E10.3213, E10.3311, E10.3312, E10.3313, E10.3411, E10.3412, E10.3413, E10.3511, E10.3512, E10.3513, E10.3521, E10.3522, E10.3523, E11.3211, E11.3212, E11.3213, E11.3311, E11.3312, E11.3313, E11.3411, E11.3412, E11.3413, E11.3511, E11.3512 and E11.3513. <b>Under ICD-10 Codes That Support Medical Necessity</b> deleted ICD-10 codes E10.321, E10.331, E10.341, E10.351, E11.321, E11.331, E11.341 and E11.351.
01/04/2016	R1	Under Article Text added the specific HCPCS code for fluocinolone acetonide intravitreal implant 0.19 mg J7313. Removed required information for not otherwise specified code.

## Associated Documents

### Related Local Coverage Document(s)

N/A

### Related National Coverage Document(s)

N/A

### Statutory Requirements URL(s)

Title XVIII of the Social Security Act §1862(a)(1)(A)

### Rules and Regulations URL(s)

N/A

### CMS Manual Explanations URL(s)

N/A

### Other URL(s)

N/A

### Public Version(s)

Updated on 10/28/2019 with effective dates 11/07/2019 - N/A

Updated on 09/26/2019 with effective dates 10/03/2019 - N/A

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## Keywords

- Iluvien