

Medical Drug Clinical Criteria

Subject:	Intravitreal Corticosteroid Implants		
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Overview

This document addresses the use of intravitreal corticosteroid implants. The following agents are included:

- Ozurdex (dexamethasone intravitreal implant)
- Retisert (fluocinolone acetonide intravitreal implant)
- Yutiq (fluocinolone acetonide intravitreal implant)
- Iluvien (fluocinolone acetonide intravitreal implant)

Intravitreal corticosteroid implants are drug delivery systems. When surgically implanted in the eye, the resultant effect is sustained release of a corticosteroid. These agents are approved to treat the following conditions:

- Diabetic macular edema (Ozurdex, Iluvien)
- Non-infectious posterior uveitis (Retisert, Ozurdex, Yutiq)
- Macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) (Ozurdex)

Diabetic macular edema (DME) results from retinal microvascular changes that compromise the blood-retinal barrier, causing leakage of plasma constituents into the surrounding retina and, consequently, retinal edema. Diabetes is a leading cause of new blindness in the United States, with clinically significant macular edema greatly contributing to this vision loss. Macular edema can result from Retinal vein occlusion (RVO). RVO is a common vascular disorder of the retina and is one of the most common causes of vision loss after diabetic retinopathy. It is classified according to where the occlusion is located. Obstruction at a branch of the retinal vein is referred to as BRVO and obstruction of the retinal vein at the optic nerve is referred to as CRVO. Intravitreal anti-vascular endothelial growth factor agents, laser photocoagulation, and intravitreal steroids may be considered for managing macular edema associated with with diabetes or RVO.

Uveitis is a broad term referring to a number of conditions that produce inflammation of the uvea, the vascular layer of the eye sandwiched between the sclera and the retina. Uveitis may affect any part of the uvea, including the anterior (iritis), intermediate (pars planitis), posterior (choroiditis), or the entire uvea (pan-uveitis). Uveitis may affect one or both eyes. Potential causes of uveitis are autoimmune disorders including sarcoidosis, infection, or exposure to toxins. However, the cause remains unknown in most individuals.

Posterior uveitis primarily involves the choroid. Symptoms may include redness of the eye, blurred vision, sensitivity to light, dark floating spots in the vision, and eye pain. The inflammation may lead to areas of scarring on the choroid and retina with corresponding areas of vision loss. Posterior uveitis may follow a systemic infection or occur in association with an autoimmune disease. Treatment of infectious uveitis involves treating the underlying condition; autoimmune diseases may require various forms of immunosuppression. Non-infectious posterior uveitis may be treated with periocular or intraocular glucocorticoid injection or systemic therapy. Intraocular steroid implants are an alternative to systemic therapy, but carry warnings for increased ocular pressure, glaucoma, and cataracts.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Retisert, Yutiq (fluocinolone acetonide intravitreal implant)

Requests for Retisert or Yutiq (fluocinolone acetonide intravitreal implant) may be approved if the following criteria are met:

- I. Individual has a diagnosis of chronic (duration of 1 year or more) non-infectious uveitis affecting the posterior segment of the eye.

Requests for Retisert or Yutiq (fluocinolone acetonide intravitreal implant) may not be approved for the following criteria:

- I. Individual has active viral diseases of cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella; **OR**
- II. Individual has active bacterial, mycobacterial or fungal infections of the eye; **OR**
- III. When the above criteria are not met and for all other indications.

Ozurdex (dexamethasone intravitreal implant)

Requests for Ozurdex (dexamethasone intravitreal implant) may be approved if the following criteria are met:

- I. Individual has a diagnosis of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); **OR**
- II. Individual has a diagnosis of chronic non-infectious uveitis (duration of 1 year or more) affecting the posterior segment of the eye; **OR**
- III. Individual has a diagnosis of diabetic macular edema.

Requests for Ozurdex (dexamethasone intravitreal implant) may not be approved for the following:

- I. Individual has ocular or periocular infections, including most viral diseases of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacteria infections, and fungal diseases; **OR**
- II. Individual has a diagnosis of glaucoma with a cup to disc ration of greater than 0.8; **OR**
- III. Individual has a torn or ruptured posterior lens capsule (NOTE: laser posterior capsulotomy in pseudophakic individuals is not a contraindication); **OR**
- IV. When the above criteria are not met and for all other indications.

Iluvien (fluocinolone acetonide intravitreal implant)

Requests for Iluvien (fluocinolone acetonide intravitreal implant) may be approved if the following criteria are met:

- I. Individual has a diagnosis of diabetic macular edema; **AND**
- II. Individual has previously been treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

Requests for Iluvien (fluocinolone acetonide intravitreal implant) may not be approved for the following criteria:

- I. Individual has active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva (such as epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella), mycobacterial infections and fungal diseases; **OR**
- II. Individual has glaucoma with a cup to disc ratio of greater than 0.8; **OR**
- III. When the above criteria are not met and for all other indications.

Quantity Limits

Intravitreal Corticosteroid Implants Quantity Limits

Drug	Limit
Iluvien (fluocinolone acetonide) 0.19 mg implant	One intravitreal implant (0.19 mg) per eye; each eye may be treated as frequently as every 36 months
Ozurdex (dexamethasone) 0.7 mg implant	One intravitreal implant (0.7 mg) per eye
Retisert (fluocinolone acetonide) 0.59 mg implant	One intravitreal implant (0.59 mg) per eye; each implant may be replaced following depletion of fluocinolone acetonide as evidenced by recurrence of uveitis
Yutiq (fluocinolone acetonide) 0.18 mg implant	One intravitreal implant (0.18 mg) per eye; each eye may be treated as frequently as every 36 months

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Fluocinolone acetonide implant (Retisert)

CPT

67027 Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous [when specified as fluocinolone acetonide implant Retisert]
**Inclusion of this code in the clinical policy is informational only and does not denote a requirement for pre or post service medical necessity review.*

HCPCS

J7311 Fluocinolone acetonide, intravitreal implant [Retisert]

ICD-10 Procedure

08H033Z Insertion of infusion device into right eye, percutaneous approach [when specified as Retisert implantation]
08H133Z Insertion of infusion device into left eye, percutaneous approach [when specified as Retisert implantation]

ICD-10 Diagnosis

H30.001-H30.049 Focal chorioretinal inflammation
H30.101-H30.149 Disseminated chorioretinal inflammation
H30.90-H30.93 Unspecified chorioretinal inflammation

Fluocinolone acetonide implant (Iluvien)

CPT

67028 Intravitreal injection of a pharmacologic agent [when specified as fluocinolone acetonide implant Iluvien]
**Inclusion of this code in the clinical policy is informational only and does not denote a requirement for pre or post service medical necessity review.*

HCPCS

J7313 Injection, fluocinolone acetonide intravitreal implant, 0.01 mg [Iluvien]

ICD-10 Diagnosis

E08.311-
E08.3519 Diabetes mellitus due to underlying condition with diabetic retinopathy with macular edema [includes only codes E08.311 and ranges E08.3211-E08.3219, E08.3311-E08.3319, E08.3411-E08.3419, E08.3511-E08.3519]
E09.311-
E09.3519 Drug or chemical induced diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E09.311 and ranges E09.3211-E09.3219, E09.3311-E09.3319, E09.3411-E09.3419, E09.3511-E09.3519]
E10.311-
E10.3519 Type 1 diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E10.311 and ranges E10.3211-E10.3219, E10.3311-E10.3319, E10.3411-E10.3419, E10.3511-E10.3519]
E11.311-
E11.3519 Type 2 diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E11.311 and ranges E11.3211-E11.3219, E11.3311-E11.3319, E11.3411-E11.3419, E11.3511-E11.3519]
E13.311-
E13.3519 Other specified diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E13.311 and ranges E13.3211-E13.3219, E13.3311-E13.3319, E13.3411-E13.3419, E13.3511-E13.3519]

Dexamethasone implant (Ozurdex)

CPT

67028 Intravitreal injection of a pharmacologic agent [when specified as intravitreal injection of dexamethasone implant Ozurdex]
**Inclusion of this code in the clinical policy is informational only and does not denote a requirement for pre or post service medical necessity review.*

HCPCS

J7312 Injection, dexamethasone intravitreal implant, 0.1 mg [Ozurdex]

ICD-10 Diagnosis

E08.311-
E08.3519 Diabetes mellitus due to underlying condition with diabetic retinopathy with macular edema [includes only codes E08.311 and ranges E08.3211-E08.3219, E08.3311-E08.3319, E08.3411-E08.3419, E08.3511-E08.3519]

E09.311- E09.3519	Drug or chemical induced diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E09.311 and ranges E09.3211-E09.3219, E09.3311-E09.3319, E09.3411-E09.3419, E09.3511-E09.3519]
E10.311- E10.3519	Type 1 diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E10.311 and ranges E10.3211-E10.3219, E10.3311-E10.3319, E10.3411-E10.3419, E10.3511-E10.3519]
E11.311- E11.3519	Type 2 diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E11.311 and ranges E11.3211-E11.3219, E11.3311-E11.3319, E11.3411-E11.3419, E11.3511-E11.3519]
E13.311- E13.3519	Other specified diabetes mellitus with diabetic retinopathy with macular edema [includes only codes E13.311 and ranges E13.3211-E13.3219, E13.3311-E13.3319, E13.3411-E13.3419, E13.3511-E13.3519]
H30.001-H30.049	Focal chorioretinal inflammation
H30.101-H30.149	Disseminated chorioretinal inflammation
H30.90-H30.93	Unspecified chorioretinal inflammation
H34.8110	Central retinal vein occlusion, right eye, with macular edema
H34.8120	Central retinal vein occlusion, left eye, with macular edema
H34.8130	Central retinal vein occlusion, bilateral, with macular edema
H34.8190	Central retinal vein occlusion, unspecified eye, with macular edema
H34.8310	Tributary (branch) retinal vein occlusion, right eye, with macular edema
H34.8320	Tributary (branch) retinal vein occlusion, left eye, with macular edema
H34.8330	Tributary (branch) retinal vein occlusion, bilateral, with macular edema
H34.8390	Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema

Fluocinolone acetonide implant (Yutiq)

CPT

67027	Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous [when specified as fluocinolone acetonide implant [Yutiq] *Inclusion of this code in the clinical policy is informational only and does not denote a requirement for pre or post service medical necessity review.
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ICD-10 Procedure

08H033Z	Insertion of infusion device into right eye, percutaneous approach [when specified as Yutiq implantation]
08H133Z	Insertion of infusion device into left eye, percutaneous approach [when specified as Yutiq implantation]

HCPCS

J7314	Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg [Yutiq] (Effective 10/1/19)
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ICD-10 Diagnosis

H30.001-H30.049	Focal chorioretinal inflammation
H30.101-H30.149	Disseminated chorioretinal inflammation
H30.90-H30.93	Unspecified chorioretinal inflammation

Document History

Reviewed: 6/12/2023

Document History:

- 06/12/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 06/13/2022 – Annual Review: Wording and formatting updates. Coding Reviewed: No changes.
- 06/14/2021 – Annual Review: No Changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: Remove frequency limit on Ozurdex quantity limit. Coding Reviewed: No changes.
- 08/16/2019 – Annual review: Wording and formatting changes; add quantity limit for new agent Yutiq. Coding Reviewed: Added HCPCS code J7314 for Yutiq (Effective 10/1/19) Delete J3490 when specified as Yutiq (Effective 10/1/19)
- 06/10/2019 – Selected review: Updated Retisert PA to include Yutiq. Coding Reviewed: Added HCPCS J3490, ICD-10 DX codes H30.001-H30.049, H30.101-H30.149, H30.90-H30.93, CPT code 67027, ICD-10 procedure codes 08H033Z, 08H133Z
- 11/09/2018 – Coding review: no changes needed
- 08/17/2018 – Annual review: Initial review of intravitreal corticosteroid implants; updated Iluvien to require trial of corticosteroids without raise in intraocular pressure per label.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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