Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Intravitreal Corticosteroid Implants: [Iluvien (fluocinolone acetonide intravitreal), Retisert (fluocinolone acetonide intravitreal), Yutiq (fluocinolone acetonide intravitreal), Ozurdex (dexamethasone intravitreal implant)]	MP-RX-FP-43-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

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

Background Information

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)

Mechanism of action

Corticosteroids, has been shown to suppress inflammation by inhibiting multiple inflammatory cytokines resulting in decreased edema, fibrin deposition, capillary leakage and migration of inflammatory cells.

Approved Indications

A. 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

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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 maybe considered for managing macular edema associated with with diabetes or RVO.

B. 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.

C. 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.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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Fluocinolone acetonide implant (Retisert)

HCPCS	Description
J7311	Fluocinolone acetonide, intravitreal implant [Retisert]

ICD-10 Procedure	Description
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	Description
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)

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

ICD-10 Diagnosis	Description
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]

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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)

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

ICD-10 Diagnosis	Description
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

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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)

HCPCS	Description
J7314	Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg [Yutiq] (Effective 10/1/19)

ICD-10 Procedure	Description
08H033Z	Insertion of infusion device into right eye, percutaneous approach [when specified as Yutiq implantation]
08H133Z	Insertion of infusion device into right eye, percutaneous approach [when specified as Yutiq implantation]

ICD-10 Diagnosis	Description
H30.001-H30.049	Focal chorioretinal inflammation
H30.101-H30.149	Disseminated chorioretinal inflammation
H30.90-H30.93	Unspecified chorioretinal inflammation

Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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.

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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 indication

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 6/12/23