Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Intravitreal Corticosteroid Implants: dexamethasone intravitreal implant (Ozurdex®), fluocinolone acetonide intravitreal implant (Retisert®), fluocinolone acetonide intravitreal implant (Yutiq®), fluocinolone acetonide intravitreal implant (Iluvien®)	MP-RX-FP-43-23	☒ **MMM MA** ☒ **MMM MultiHealth**	11/30/2023 **Last Review Date:** 03/24/2026	03/24/2026 **Frequently Revision:** Annual

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 the following intravitreal corticosteroid implants drug delivery systems approved by the Food and Drug Administration (FDA) for the treatment of Diabetic Macular Edema, Non-Infectious Posterior Uveitis and Macular Edema following branch retinal vein occlusion or central vein occlusion.

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

Background Information

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

Uveitis is a broad term referring to several 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

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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.

Approved Indications

A. Ozurdex is approved by the FDA for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO), non-infectious uveitis affecting the posterior segment of the eye and for the treatment of diabetic macular edema (DME).

B. Retisert and Yutiq are approved by the FDA for the treatment of chronic non- infectious uveitis affecting the posterior segment of the eye.

C. Iluvien is approved by the FDA 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 and for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

Other Uses

A. N/A.

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.

HCPCS	Description
J7311	Fluocinolone acetonide, intravitreal implant [Retisert], 0.01 mg
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg [Iluvien]
J7312	Injection, dexamethasone intravitreal implant, 0.1 mg [Ozurdex]

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J7314	Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg [Yutiq]

ICD-10	Description
H30.001-H30.049	Focal chorioretinal inflammation
H30.101-H30.139	Disseminated chorioretinal inflammation
H30.811-H30.819	Harada's disease
H30.891-H30.899	Other chorioretinal inflammations
H30.90-H30.93	Unspecified chorioretinal inflammation
E08.311	Diabetes mellitus due to underlying condition with diabetic retinopathy with macular edema
E08.3211-E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema
E08.3311-E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema
E08.3411-E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema
E08.3511-E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
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

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H34.8390	Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema

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.

Fluocinolone acetonide (Retisert®, Yutiq®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

I. Initial requests for Retisert and Yutiq 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.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of fluocinolone acetonide (Retisert®, Yutiq®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval- Fluocinonide acetonide (Retisert, Yutiq)) if the following criteria are met:

A. Individuals are eligible for retreatment with Yutiq every 36 months based on physician's discretion after examination.

B. Individuals are eligible for retreatment with Retisert following depletion of fluocinolone acetonide as evidenced by recurrence of uveitis.

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C. Authorization Duration

i. Initial Approval Duration: Up to 12 months (Retreatment of Yutiq may be requested every 36 months)
ii. Reauthorization Approval Duration: Up to 12 months (Retreatment of Yutiq may be requested every 36 months)

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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.

Dexamethasone intravitreal implant (Ozurdex®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

I. Initial requests for Ozurdex 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.

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B. Criteria For Continuation of Therapy

i. MMM considers continuation of dexamethasone intravitreal implant (Ozurdex®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval for Ozurdex) if the following criteria are met:

A. Individuals are eligible for retreatment with Ozurdex starting from Month 6 based on physician's discretion after examination including Optical Coherence Tomography and could only receive treatment at least 6 months apart.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

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.

Fluocinolone acetonide intravitreal implant (Iluvien®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

I. Initial requests for Iluvien may be approved if the following criteria are met:

i. Individual has a diagnosis of diabetic macular edema; **AND**

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ii. Individual has previously been treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; **OR**

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

B. Criteria For Continuation of Therapy

i. MMM considers continuation of fluocinolone acetonide intravitreal implant (Iluvien®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following criteria are met:

A. Individuals are eligible for retreatment with Iluvien every 36 months based on physician's discretion after examination.

C. Authorization Duration

i. Initial Approval Duration: Up to 12 months (Retreatment of Iluvien may be requested every 36 months)

ii. Reauthorization Approval Duration: Up to 12 months (Retreatment of Iluvien may be requested every 36 months)

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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.

Limits or Restrictions

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A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. 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.

Drug	Recommended Dosing Schedule
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; each eye may be treated as frequently as every 6 months starting from Month 6 based on physician's discretion after examination including Optical Coherence Tomography
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
Exceptions	
None	

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.

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http://dailymed.nlm.nih.gov/dailymed/about.cfm.

3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. American Academy of Ophthalmology. Preferred Practice Pattern Guidelines: Diabetic Retinopathy. February 2025.
6. American Academy of Ophthalmology. Preferred Practice Pattern Guidelines: Retinal Vein Occlusions. February 2025.
7. AbbVie Inc. (n.d.). *Ozurdex® prescribing information*. Retrieved January 31, 2026, from https://www.rxabbvie.com/pdf/ozurdex_pi.pdf
8. EyePoint Pharmaceuticals. (n.d.). *Yutiq® prescribing information*. Retrieved January 31, 2026, from https://hcp.yutiq.com/prescribing-information/
9. Alimera Sciences. (n.d.). *Iluvien® prescribing information*. Retrieved January 31, 2026, from https://hcp.iluvien.com/pi/ILUVIEN-prescribing-information.pdf
10. Bausch & Lomb Incorporated. (n.d.). *Retisert® prescribing information*. Retrieved January 31, 2026, from https://pi.bausch.com/globalassets/pdf/PackageInserts/Pharma/retisert-prescribing-information.pdf

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

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Iluvien approved uses and clinical criteria to include new FDA approved indication for non-infectious uveitis. Coding Reviewed: Separated ICD-10-CM code range E08.311-E08.5519 into applicable codes based on code description (only includes codes E08.311, E08.3211-E08.2119, E08.3311-E08.3319, E08.3411-E08.3419, E08.3511-E08.3519) for Iluvien and Ozurdex. Removed codes H30.141-H30.149 from code range 5 H30.101-H30.149 for Ozurdex, Retisert and Yutiq. Added H30.811-H30.819 and H30.891-H30.899 to Ozurdex, Retisert, and Yutiq. Added H30.001-H30.049, H30.101-H30.139, H30.811-H30.819, H30.891-H30.899, H30.90-H30.93 to Iluvien. Updated references. Wording and formatting changes.	3/17/2026	03/24/2026
Annual Review	Added to clinical criteria for initial request for Iluvien: Individual is using for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Minimal changes; No coding changes.	6/9/2025	6/19/2025

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Annual Change	Added the following statement to the initial approval criteria section: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.); Added criteria for continuation of therapy; Wording and formatting changes; Added authorization duration; Coding Reviewed: Minor updates to HCPCS coding descriptions, no other changes.	2/24/2025	3/6/2025
Policy Inception	Elevance Health Medical Policy adoption	N/A	11/30/2023