

## MEDICAL POLICY – 5.01.619

# Intravitreal and Suprachoroidal Corticosteroids


BCBSA Ref. Policy: 9.03.23

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Replaces: N/A

RELATED MEDICAL POLICIES:  
None

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## Introduction

An intravitreal implant is a drug delivery system, injected or surgically implanted in the vitreous of the eye, for sustained release of drug to the posterior and intermediate segments of the eye. Intravitreal corticosteroid implants are used for a variety of inflammatory eye conditions such as diabetic macular edema, non-infectious uveitis, and retinal venous occlusions. A suprachoroidal injection administers the drug to the suprachoroidal space (SCS) which is the area that covers the outside of the posterior segment (back two-thirds) of the eye. This method of drug delivery is designed to improve exposure to the posterior segment of the eye while potentially minimizing side effects such as increases in eye pressure. The goal of both intravitreal and SCS drug treatments are to reduce inflammation in the eye while minimizing the adverse effects of the therapeutic regimen.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

Drug	Medical Necessity
<b>Ozurdex (dexamethasone intravitreal implant)</b>	<p><b>Ozurdex (dexamethasone intravitreal implant) may be considered medically necessary for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of BRVO or CRVO is confirmed by fluorescein angiogram</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The individual does NOT have any of the following contraindications: <ul style="list-style-type: none"> <li>○ Active or suspected ocular or periocular infection</li> <li>○ Glaucoma with a cup to disc ratio of greater than 0.8</li> <li>○ Torn or ruptured posterior lens capsule</li> </ul> </li> </ul> <p><b>Ozurdex (dexamethasone intravitreal implant) may be considered medically necessary for the treatment of non-infectious uveitis of the posterior segment of the eye when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have any of the following contraindications: <ul style="list-style-type: none"> <li>○ Active or suspected ocular or periocular infection</li> <li>○ Glaucoma with a cup to disc ratio of greater than 0.8</li> <li>○ Torn or ruptured posterior lens capsule</li> </ul> </li> </ul> <p><b>Ozurdex (dexamethasone intravitreal implant) may be considered medically necessary for the treatment of diabetic macular edema (DME) when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have any of the following contraindications: <ul style="list-style-type: none"> <li>○ Active or suspected ocular or periocular infection</li> <li>○ Glaucoma with a cup to disc ratio of greater than 0.8</li> </ul> </li> </ul>

Drug	Medical Necessity
	<ul style="list-style-type: none"> <li>○ Torn or ruptured posterior lens capsule</li> </ul>
<b>Iluvien (fluocinolone acetonide intravitreal implant)</b>	<p><b>Iluvien (fluocinolone acetonide intravitreal implant) may be considered medically necessary for the treatment of diabetic macular edema (DME) when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Has previously been treated with corticosteroids and did not have a clinically significant rise in intraocular pressure</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have any of the following contraindications:             <ul style="list-style-type: none"> <li>○ Active or suspected ocular or periocular infection</li> <li>○ Glaucoma with a cup to disc ratio of greater than 0.8</li> </ul> </li> </ul> <p><b>Iluvien (fluocinolone acetonide intravitreal implant) may be considered medically necessary for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Has greater than or equal to 1 year history of non-infectious uveitis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have any of the following contraindications:             <ul style="list-style-type: none"> <li>○ Active or suspected ocular or periocular infection</li> <li>○ Glaucoma with a cup to disc ratio of greater than 0.8</li> </ul> </li> </ul>
<b>Retisert (fluocinolone acetonide intravitreal implant)</b>	<p><b>Retisert (fluocinolone acetonide intravitreal implant) may be considered medically necessary for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 12 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Has greater than or equal to 1 year history of non-infectious uveitis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have active or suspected ocular or periocular infection</li> </ul>

Drug	Medical Necessity
<b>Xipere (triamcinolone acetonide injectable suspension)</b>	<p><b>Xipere (triamcinolone acetonide injectable suspension) may be considered medically necessary for the treatment of macular edema associated with uveitis when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Has a diagnosis of non-infectious uveitis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• The macular edema is secondary to uveitis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have active or suspected ocular or periocular infection</li> </ul>
<b>Yutiq (fluocinolone acetonide intravitreal implant)</b>	<p><b>Yutiq (fluocinolone acetonide intravitreal implant) may be considered medically necessary for the treatment of chronic non-infectious uveitis of the posterior segment of the eye when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The individual is aged 18 years and older</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Has greater than or equal to 1 year history of non-infectious uveitis</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Does NOT have active or suspected ocular or periocular infection</li> </ul>

Drug	Investigational
<b>As listed</b>	<p><b>The drugs listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.</b></p> <p><b>All other uses of Ozurdex (dexamethasone intravitreal implant), Iluvien (fluocinolone acetonide intravitreal implant), Retisert (fluocinolone acetonide intravitreal implant), Xipere (triamcinolone acetonide injectable suspension), and Yutiq (fluocinolone acetonide intravitreal implant) for conditions not outlined in this policy are considered investigational. This includes treatment of other inflammatory ocular conditions.</b></p>



Length of Approval	
Approval	Criteria
<b>Initial authorization</b>	<p><b>Non-formulary exception reviews and all other reviews for Ozurdex (dexamethasone intravitreal implant), Iluvien (fluocinolone acetonide intravitreal implant), Retisert (fluocinolone acetonide intravitreal implant), Xipere (triamcinolone acetonide injectable suspension), and Yutiq (fluocinolone acetonide intravitreal implant) may be approved up to 12 months.</b></p>
<b>Re-authorization criteria</b>	<p><b>Non-formulary exception reviews and all other reviews for Ozurdex (dexamethasone intravitreal implant) for the treatment of BRVO or CRVO may be approved up to 12 months when clinical benefit/response at the time of re-authorization show:</b></p> <ul style="list-style-type: none"> <li>Improvement in at least 15 letters from baseline in best corrected visual acuity (BCVA)</li> </ul> <p><b>Non-formulary exception reviews and all other reviews for Ozurdex (dexamethasone intravitreal implant) for the treatment of non-infectious uveitis of the posterior segment of the eye may be approved up to 12 months when clinical benefit/response at the time of re-authorization show:</b></p> <ul style="list-style-type: none"> <li>Reduced inflammation (vitreous haze) from baseline</li> </ul> <p><b>Non-formulary exception reviews and all other reviews for Iluvien (fluocinolone acetonide intravitreal implant), Retisert (fluocinolone acetonide intravitreal implant), and Yutiq (fluocinolone acetonide intravitreal implant) for the treatment of chronic non-infectious uveitis of the posterior segment of the eye may be approved up to 12 months when clinical benefit/response at the time of re-authorization show:</b></p> <ul style="list-style-type: none"> <li>Decrease in recurrence of uveitis during the treatment period</li> </ul> <p><b>Non-formulary exception reviews and all other reviews for Xipere (triamcinolone acetonide injectable suspension) for the treatment of macular edema associated with uveitis may be</b></p>

Length of Approval	
Approval	Criteria
	<p><b>approved up to 12 months when clinical benefit/response at the time of re-authorization show:</b></p> <ul style="list-style-type: none"> <li>Improvement in at least 15 letters from baseline in BCVA</li> </ul> <p><b>Non-formulary exception reviews and all other reviews for Ozurdex (dexamethasone intravitreal implant) and Iluvien (fluocinolone acetonide intravitreal implant) for the treatment of DME may be approved up to 12 months when clinical benefit/response at the time of re-authorization show:</b></p> <ul style="list-style-type: none"> <li>Improvement in at least 15 letters from baseline in BCVA</li> </ul>

Documentation Requirements
<p><b>The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:</b></p> <ul style="list-style-type: none"> <li>Office visit notes that contain the diagnosis, relevant history, laboratory values, physical evaluation, and medication history.</li> </ul>

## Coding

Code	Description
<b>HCPCS</b>	
J3299	Injection, triamcinolone acetonide (Xipere), 1 mg
J7311	Injection, fluocinolone acetonide, intravitreal implant (Retisert), 0.01 mg
J7312	Injection, dexamethasone, intravitreal implant (Ozurdex), 0.1 mg
J7313	Injection, fluocinolone acetonide, intravitreal implant (IluviIn), 0.01 mg
J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).



## Related Information

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### Consideration of Age

The ages noted in the policy statements are based on the Food and Drug Administration labeling for these agents.

### Benefit Application

Ozurdex (dexamethasone intravitreal implant), Iluvien (fluocinolone acetonide intravitreal implant), Retisert (fluocinolone), Xipere (triamcinolone acetonide injectable suspension), and Yutiq (fluocinolone acetonide intravitreal implant) are managed under the medical benefit.

## Evidence Review

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### Description

#### Retinal Vein Occlusion

Retinal vein occlusion is a blockage of a portion of the venous circulation that drains the retina and is second only to diabetic retinopathy as the most common retinal vascular cause of visual loss. It generally does not occur until later in life and may have several causes, including hypertension, atherosclerosis, diabetes, and glaucoma. When a blockage occurs, pressure builds up in the capillaries causing hemorrhages and leakage of fluid and blood. This can lead to macular edema (ME) and ischemia of the macula. There are two basic types of retinal vein occlusion: central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). Central retinal vein occlusion is obstruction of the retinal vein at the optic nerve and BRVO is obstruction of a portion of the venous circulation that drains the retina.

CRVO is a common retinal vascular disorder. The exact etiology is unknown, however may be caused by arteriosclerotic changes in the central retinal artery or from a thrombotic occlusion of the central retinal vein. Occlusion of the central retinal vein leads to backup of the blood in the retinal venous system and increases resistance to the venous blood flow. This increased resistance causes stagnation of the blood and ischemia to the retina. Ischemic damage to the



retina stimulates increased production of vascular endothelial growth factor (VEGF), and increased levels of VEGF stimulate neovascularization of the posterior and anterior segment of the eye.

In BRVO the blockage occurs in a smaller branch of the vessels that connect to the central retinal vein. BRVO occurs three times more often than CRVO and may include both systemic factors (e.g., hypertension) as well as local anatomic factors (e.g., arterio-venous crossings).

For individuals with ME after retinal vein occlusion who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes 2 randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Compared with sham controls, implants resulted in clinically meaningful improvements in visual acuity within 1 to 3 months postimplant and improvement in vision occurred faster. The difference in the proportion of individuals with gain of 15 or more letters in best-corrected visual acuity from baseline was more than 10% in favor implants versus sham in both studies at 30, 60 and 90 days, but not at 180 days postimplant. Use of implants resulted in higher incidences of cataracts and elevated intraocular pressure. Several additional RCTs and a meta-analysis have evaluated the comparative effects of dexamethasone intravitreal implants versus other therapies and found mixed results. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. For individuals with ME after retinal vein occlusion who receive an intravitreal fluocinolone acetonide implant (0.59 mg), no studies were identified. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Uveitis

Uveitis encompasses a variety of conditions, of either infectious or noninfectious etiologies, that are characterized by inflammation of any part of the uveal tract of the eye (iris, ciliary body, choroid). Infectious etiologies include syphilis, toxoplasmosis, cytomegalovirus retinitis, and candidiasis. Chronic inflammation associated with posterior segment uveitis can lead to cataracts and glaucoma and to structural damage to the eye resulting in severe and permanent vision loss. The primary goal of therapy for uveitis is to preserve vision. Noninfectious uveitis typically responds well to corticosteroid treatment.

For individuals with chronic noninfectious intermediate or posterior uveitis who receive an intravitreal fluocinolone acetonide implant (0.59 mg), the evidence includes four RCTs. Relevant



outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Two of the four RCTs compared two doses of implants, and two trials compared implants with systemic steroids (and immunosuppression when indicated). All trials supported the efficacy of intravitreal fluocinolone acetonide implants in preventing recurrence and improving visual acuity over four-year follow-up. The head-to-head trial comparing implants with systemic corticosteroids did not show substantial superiority in the overall effectiveness of either approach. After 24 and 54 months of follow-up, visual acuity improved from baseline in the implant groups compared with the systematic therapy groups by +6.0 and +3.2 letters ( $p=0.16$ ) and +2.4 and 3.1 letters ( $p=0.073$ ), respectively. However, nearly all phakic individuals receiving implants developed cataracts and required cataract surgery. Further, most also developed glaucoma, with 75% of individuals requiring intraocular pressure lowering medications and 35% requiring filtering surgeries. Systemic adverse events such as hyperlipidemia, diabetes, osteoporosis, fractures, and blood count/chemistry abnormalities were infrequent and not statistically distinguishable between groups. The incidence of hypertension was greater in the systemic therapy group (27%) than in the implant group (13%), but rates of antihypertensive treatment initiation did not differ. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with noninfectious intermediate or posterior uveitis who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Results of this trial at eight weeks showed that the implant was effective in reducing inflammation (the proportion of eyes with no inflammation was 47% and 12% with implant and sham, respectively) and resulted in clinically meaningful improvement in vision at week 8 compared with sham controls (the proportion of individuals with a gain of  $\geq 15$  letters in best-corrected visual acuity from baseline was  $>40\%$  with implants and 10% with sham). Further, at week 26, individuals treated with implants reported meaningful increases in vision-related functioning. The major limitation of this trial was its lack of long-term follow-up. Use of implants resulted in higher incidences of cataracts and elevated intraocular pressure. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with chronic noninfectious intermediate or posterior uveitis who receive an intravitreal fluocinolone acetonide implant (0.59 mg), the evidence includes four RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Two of the four RCTs compared two doses of implants, and two trials compared implants with systemic steroids (and immunosuppression when indicated). All trials supported the efficacy of intravitreal fluocinolone acetonide implants in preventing recurrence and improving visual acuity over four-year follow-up. The head-to-head trial

comparing implants with systemic corticosteroids did not show substantial superiority in the overall effectiveness of either approach. After 24 and 54 months of follow-up, visual acuity improved from baseline in the implant groups compared with the systematic therapy groups by +6.0 and +3.2 letters ( $p=0.16$ ) and +2.4 and 3.1 letters ( $p=0.073$ ), respectively. However, nearly all phakic individuals receiving implants developed cataracts and required cataract surgery. Further, most also developed glaucoma, with 75% of individuals requiring intraocular pressure lowering medications and 35% requiring filtering surgeries. Systemic adverse events such as hyperlipidemia, diabetes, osteoporosis, fractures, and blood count/chemistry abnormalities were infrequent and not statistically distinguishable between groups. The incidence of hypertension was greater in the systemic therapy group (27%) than in the implant group (13%), but rates of antihypertensive treatment initiation did not differ. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with chronic noninfectious posterior uveitis affecting the posterior segment of the eye and who receive intravitreal fluocinolone acetonide implant (0.18 mg, Yutiq), the evidence includes two pivotal RCTs. Relevant outcomes are symptom improvement, change in disease status, functional status, and quality of life. Harmful outcomes of interest are treatment-related morbidity. Both RCTs consistently found statistically significantly lower uveitis recurrence rates for intravitreal fluocinolone acetonide implant (0.18 mg, Yutiq) at both six and 12 months. However, serious limitations of these findings include inconsistency in the magnitude of the benefit at 12 months (odds ratio 67.09; 95% confidence interval 8.81-511.06 in published RCT and odds ratio 3.04; 95% confidence interval 1.52, 6.08 in the unpublished RCT) and, with more imputed recurrences in the sham groups than the treatment groups, we also can't rule out an overestimation of the treatment effect. For the remainder of key outcomes, results were inconsistent between RCTs, appearing more favorable in the published trial. Most notable were the differences between RCTs in mean change in best-corrected visual acuity at 12 months (higher for fluocinolone acetonide in the published trial, lower in the unpublished trials) and risk of increased intraocular pressure within 12 months (increased risk in the unpublished trial, but not in the published trial). Due to these inconsistencies and serious methodological limitations the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For the treatment of ME associated with non-infectious uveitis there is one phase 3 masked, randomized trial that was conducted to evaluate the safety and efficacy of suprachoroidally injected triamcinolone acetonide formulation (CLS-TA). One hundred sixty individuals with ME secondary to noninfectious uveitis were enrolled and individuals were required to have a best-corrected visual acuity (BCVA) of five or more Early Treatment Diabetic Retinopathy Study (ETDRS) letters (Snellen equivalent, 20/800) and 70 or fewer ETDRS letters read (Snellen equivalent, 20/40) in the study eye. The primary end point was improvement from baseline of 15

or more ETDRS letters in BCVA at week 24. The secondary end point was reduction from baseline in central subfield thickness (CST) at week 24. In the CLS-TA arm, 47% of individuals gained 15 or more ETDRS letters in BCVA versus 16% in the control arm ( $P < 0.001$ ), meeting the primary end point. Mean reductions in CST from baseline were 153 mm versus 18 mm ( $P < 0.001$ ). No serious adverse events (AEs) related to treatment were reported. Corticosteroid associated AEs of elevated intraocular pressure occurred in 11.5% and 15.6% of the CLS-TA and control groups, respectively. Cataract AE rates were comparable (7.3% and 6.3%, respectively).

## Diabetic Macular Edema

For individuals with diabetic macular edema (DME) who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes three RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Compared with sham control, two identically designed RCTs showed clinically meaningful improvements in vision with dexamethasone implants that peaked at three months and maintained 39 months (with retreatment). The difference in the proportion of individuals with a gain of 15 or more letters in best-corrected visual acuity from baseline was 9.3% and 13.0% in the two trials, respectively, favoring implant versus sham at 39 months postimplant. Subgroup analysis of these trials showed greater improvements in visual acuity in individuals who were pseudophakic compared with those who were phakic. Additionally, evidence from various small and/or short-term trials and retrospective studies have found that, compared with primarily antivascular endothelial growth factor treatments, intravitreal dexamethasone implant (0.7 mg) was consistently associated with larger reductions in retinal thickness, but visual acuity changes were similar between treatment groups. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with DME who receive an intravitreal dexamethasone implant (0.7 mg) plus antivascular endothelial growth factor therapy, the evidence includes two RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Findings from both RCTs were consistent in demonstrating that although adding dexamethasone to an antivascular endothelial growth factor treatment can lead to a greater mean reduction in central subfield thickness, it does not improve visual acuity and can lead to a higher risk of intraocular pressure elevation. Based on the consistent lack of improvement in visual acuity, increased risk of intraocular pressure elevation, and imprecision, these RCTs provide insufficient evidence to determine that the technology results in an improvement in the net health outcome. For individuals with DME who receive an intravitreal dexamethasone implant (0.7 mg) plus laser photocoagulation, the evidence includes RCT.

Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity.

Diabetic retinopathy is a common microvascular complication of diabetes and a leading cause of blindness in adults. The two most serious complications for vision are DME and proliferative diabetic retinopathy. At its earliest stage (nonproliferative retinopathy), microaneurysms occur. As the disease progresses, blood vessels that provide nourishment to the retina are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). Severe vision loss with proliferative retinopathy arises from leakage of blood into the vitreous. DME is characterized by swelling of the macula due to gradual leakage of fluids from blood vessels and breakdown of the blood-retinal barrier. Moderate vision loss can arise from the fluid accumulating in the center of the macula (ME) during the proliferative or nonproliferative stages of the disease. Although proliferative disease is the main blinding complication of diabetic retinopathy, ME is more frequent and is the leading cause of moderate vision loss in people with diabetes. Tight glycemic and blood pressure control is the first line of treatment to control diabetic retinopathy, followed by laser photocoagulation for individuals whose retinopathy is approaching the high-risk stage. Although laser photocoagulation is effective at slowing the progression of retinopathy and reducing visual loss, it does not restore lost vision.

For individuals with refractory (persistent or recurrent) DME who receive an intravitreal fluocinolone acetonide implant (0.59 mg), the evidence includes one RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Compared with the standard of care (as needed laser or observation), a greater proportion of individuals with implants reported clinically significant improvement in vision at six months (1.4% vs. 16.8% respectively) and subsequent time points assessed but not at or beyond 30 months of follow-up. Ninety percent of individuals with phakic eyes who received implants required cataract surgery, and 60% developed elevated intraocular pressure. Due to the substantial increase in AEs and availability of agents with better tolerability profiles (e.g., antivascular endothelial growth factor inhibitors), implant use in DME is questionable. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with DME who receive an intravitreal fluocinolone acetonide implant (0.19 mg), the evidence includes two RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Implant-treated eyes showed clinically meaningful improvements in the vision at two and three years postimplant. The percentage of individuals who gained 15 letters or more was 28.7% in the implant group versus 18.9% in the sham group at three years. Subgroup analysis showed greater improvements in visual acuity in individuals who were pseudophakic compared with those who



were phakic (difference in mean change in number of letters at two years from baseline was 5.6 letters in pseudophakic individuals vs. one letter in phakic individuals). A major limitation of these implants is that nearly 80% of all phakic individuals will develop cataracts and will require cataract surgery. Further, intraocular pressure was elevated in 34% of individuals who received this implant compared with 10% of controls. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

## **2022 Update**

Reviewed prescribing information for all drugs listed in policy and information on the diagnosis of retinal vein occlusion. No new information was identified that would require changes to this policy.

## **2023 Update**

Reviewed prescribing information for all drugs listed in policy and information on the diagnosis of retinal vein occlusion. No new information was identified that would require changes to this policy.

## **2024 Update**

Reviewed prescribing information for all drugs listed in policy. No new information was identified that would require changes to this policy.

## **2025 Update**

Reviewed prescribing information for all drugs listed in policy. Added a new indication to Iluvien (fluocinolone acetonide intravitreal implant) for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.



## References

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## History

Date	Comments
11/01/21	New policy, approved October 12, 2021, effective for dates of service on or after February 4, 2022, following 90-day provider notification. Coverage criteria added for Ozurdex (dexamethasone intravitreal implant) for the treatment of macular edema following BRVO or CRVO, treatment of non-infectious uveitis, and for the treatment of DME. Coverage criteria added for Iluvien (fluocinolone acetonide intravitreal implant)



Date	Comments
	for the treatment of DME. Coverage criteria added for Retisert (fluocinolone) for the treatment of non-infectious uveitis. Coverage criteria added for Yutiq (fluocinolone acetonide intravitreal implant) for the treatment of non-infectious uveitis.
06/01/22	Interim Review, approved May 10, 2022. Updated policy name from "Intravitreal Corticosteroids" to "Intravitreal and Suprachoroidal Corticosteroids". Added coverage criteria for Xipere (triamcinolone acetonide injectable suspension) for the treatment of macular edema associated with uveitis. Added HCPCS codes C9092 and J3490.
07/01/22	Coding update. Added HCPCS code J3299. Removed HCPCS code J3490.
01/01/23	Annual Review, approved December 12, 2022. No changes to policy statements. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/23	Annual Review, approved October 9, 2023. No changes to policy statements. Removed termed HCPCS code C9092 from policy.
09/01/24	Annual Review, approved August 26, 2024. No changes to policy statements.
05/01/25	Annual Review, approved April 8, 2025. Added a new indication to Iluvien (fluocinolone acetonide intravitreal implant) for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

