Policy Name	Clinical Policy – Corticosteroid Implants and Injections
Policy Number	1346.00
Department	Clinical Product & Development
Subcategory	Medical Management
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Current Effective Date	10/01/2024

Company Entities Supported (Select All that Apply):
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
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ACRONYMS	
RVO	Retinal vein occlusion

PURPOSE

To provide the clinical criteria to support the indication(s) for corticosteroid implants and injectables. Applicable procedure codes are also defined.

POLICY

A. Background

Corticosteroids suppress intra-ocular inflammation. The policy addresses the corticosteroids which may be administered through an injection or an implant of the drug delivery system. Table 1 outlines the FDA approved conditions for these drugs. The efficacy of corticosteroids in the treatment of various conditions is evaluated through improvements in visual acuity, resolution of the macular edema, and the ability to reduce oral corticosteroids.

B. Medically Necessary

1. **Iluvien** (fluocinolone acetonide intravitreal implant 0.19 mg) may be medically necessary[1] for the treatment of diabetic macular edema.

[1] Campochiaro, 2011

a. Initial treatment with Iluvien may be medically necessary when:
   i. There is a diagnosis of diabetic macular edema confirmed by either OCT or IVFA; and,
   ii. The patient has had prior treatment trials with corticosteroids either as topical therapy, intravitreal injection or intravitreal implant, and,
   iii. The medical plan includes intraocular pressure control with or without glaucoma treatment.[2]

b. Retreatment with Iluvien may be medically necessary when[3]:
   i. Diabetic macular edema has persisted for at least twelve months; and,
   ii. There is a loss of five letters in BCVA; or,
   iii. There is evidence of worsening edema such as an increase in retinal thickness compared to prior best status; and,
   iv. The medical plan includes intraocular pressure control with or without glaucoma treatment.

c. Iluvien is contraindicated when:
   i. There is evidence of coincident viral or fungal infection; or,
   ii. The posterior lens capsule is not intact; or,
   iii. The pattern of uveitis is iritis or iridocyclitis; or,
   iv. The patient has hypersensitivity to fluocinolone acetonide or any of the components of Iluvien.

2. Ozurdex (dexamethasone intravitreal implant 0.7mg) may be medically necessary[4] for the treatment of diabetic macular edema, macular edema due to retinal vein occlusion, cystoid macular edema following cataract surgery, and noninfectious posterior uveitis.

a. Initial treatment for Ozurdex may be medically necessary when:
   i. The comprehensive ophthalmic evaluation including either Ophthalmic Computed Tomography (OCT) or intravenous fluorescein angiography (IVFA) confirms the indicated diagnosis(es) above; and,
   ii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

b. Retreatment with Ozurdex may be considered medically necessary when[5]:
   i. At least three months have passed since the last injection of Ozurdex; and,
   ii. The initial diagnosis(es) are still present; and,
   iii. The medial plan includes intraocular pressure control with or without glaucoma treatment; and,
   iv. OCT documents persistent central retinal thickness; or,
   v. OCT documents persistent retinal cysts; or,
   vi. OCT documents persistent retinal thickness outside the central subfield.

[2] Seibold, 2022.
[3] Campochiaro, 2011 and Kodijikian, 2021
[4] Boyer, 2014, and Allergan, 2020
[5] Boyer, 2014

c. Ozurdex will be excluded from treatment when:
   i. There is evidence of co-incident viral or fungal infection; or,
   ii. The posterior lens capsule is not intact; or,
   iii. The pattern of uveitis is iritis or iridocyclitis; or,
   iv. The patient has hypersensitivity to dexamethasone or any of the components of Ozurdex.

3. Retisert (fluocinolone acetonide intravitreal implant 0.59 mg) may be medically necessary for the treatment of chronic posterior non-infectious uveitis of at least one year duration.[6] Retisert may also be medically necessary as an off label treatment for diabetic macular edema.

a. Initial treatment of Retisert may be medically necessary when:
   i. A comprehensive ophthalmic evaluation with OCT or IVFA supports the diagnosis(es) of chronic posterior non-infectious uveitis or diabetic macular edema; and,
   ii. The documented medical history shows the posterior non-infectious uveitis as being at least one year duration; and,
   iii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

b. Retreatment with Retisert may be considered medically necessary when:
   i. At least 30 months have elapsed from initial therapy; and,
   ii. Documentation from the initial therapy demonstrates effectiveness in reducing the degree of chronic posterior inflammation or diabetic macular edema; and,
   iii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

c. Retisert will be excluded from treatment if:
   i. There is coincident viral or fungal infection; or,
   ii. The patient has a known or suspected hypersensitivity to Retisert, or any of its components, or to other corticosteroids.

4. Triesence (triamcinolone acetonide injectable suspension 40 mg/mL is indicated for, uveitis, sympathetic ophthalmia, and diabetic macula edema. It is also indicated for other ocular inflammatory conditions (see Table 1) that have been unresponsive to topical corticosteroids.[7]

a. The initial treatment of Triesence may be medically necessary when:
   i. The initial treatment plan includes a comprehensive ophthalmic evaluation with OCT or IVFA to support the diagnosis(es) listed above; and,
   ii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

b. Retreatment with Triesence may be medically necessary after 3-4 months and when:

[6] Campochiaro, 2020.
[7] FDA. 2023.

i. At least three months have passed since the last injection; and,
ii. The initial diagnosis is still present, and,
iii. The initial therapy demonstrated effectiveness; and,
iv. The medical plan includes intraocular pressure control with or without glaucoma treatment.

c. Triesence is contraindicated for patients with:
i. Known or suspected ocular infection or systemic fungal infection; or,
ii. Known or suspected hypersensitivity to triamcinolone acetonide or any component of the product.

5. Xipere (triamcinolone acetonide injectable suspension 40 mg/ml may be medically necessary for macular edema with noninfectious uveitis.[8]

a. Initial treatment with Xipere may be medically necessary when:
i. The initial treatment plan includes a comprehensive ophthalmic evaluation with OCT or IVFA to support the diagnoses of macular edema with noninfectious uveitis; and,
ii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

b. Retreatment with Xipere may be medically necessary after 3-4 months and when:
i. At least three months have passed since the last injection; and,
ii. The initial diagnosis is still present; and,
iii. The initial therapy demonstrated effectiveness; and,
iv. The medical plan includes intraocular pressure control with or without glaucoma treatment.

c. Xipere is contraindicated for patients with:
i. Ocular or periocular infections including bacterial, fungal, and viral infections; or,
ii. Known or suspected hypersensitivity to triamcinolone acetonide or any component of the product.

6. Yutiq (fluocinolone acetonide intravitreal implant 0.18mg) may be medically necessary for the treatment of chronic non-infectious posterior uveitis of at least one year duration.[9]

a. Initial treatment of Yutiq may be considered medically necessary when:
i. A comprehensive ophthalmic evaluation with OCT or IVFA supports the diagnosis(es) as above; and,
ii. For chronic non-infectious posterior uveitis, the medical history documents the condition to be at least one year duration; and,
iii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

b. Retreatment with Yutiq may be medically necessary when:
i. At least 36 months have elapsed from initial therapy; and,

[8] FDA, 2023.
[9] Boyer, 2014.

ii. Documentation from the initial therapy demonstrates effectiveness in reducing the initial diagnosis(es).
iii. The medical plan includes intraocular pressure control with or without glaucoma treatment.

c. Yutiq is excluded from treatment if:
i. There is coincident viral or fungal infection present; or,
ii. The patient has known or suspected hypersensitivity to Yutiq or any of its components.

TABLE 1

Diagnosis	Iluvien fluocino-lone acetonide injection	Ozurdex dexamethasone implant	Retisert fluocino-lone acetonide implant	Triesence triamcinolone acetonide injection	Xipere triamcinolone acetonide injection	Yutiq fluocinolone acetonide implant
Chronic noninfectious uveitis (duration of 1 year or more)		X	X	X		X
CME following cataract surgery		X		X		
Diabetic macula edema	X	X	X	X		
Macula edema and noninfectious uveitis		X			X	
Non-infectious uveitis		X		X		
RVO with edema		X		X		
Sympathetic ophthalmia		X		X		

C. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale for it as in requirements above. All items must be available upon request to initiate or sustain previous

payments. For any retrospective review, a full operative report and/or the clinical care plan is required.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

The following documentation supports the medical necessity of corticosteroid implants and injections:

a. An examination of the anterior segment and posterior segment with documented pertinent findings; and,
b. The interpretation and report from diagnostic studies performed such as OCT and fluorescein angiogram that include:
c. Findings; and,
d. Clinical diagnosis; and,
e. Comparative data (e.g., condition is deteriorating, improving or unchanged); and,
f. Clinical Management; and,
g. Impression/plan must state the specific corticosteroid to be injected intravitreally; and dates and frequency of administration including past uses; and,
h. If the posterior segment cannot be visualized, this should be noted in the examination and a B scan completed with the findings, diagnosis, comparative data, and clinical management.

D. Procedural Detail

CPT / HCPCS Codes	
67028	Intravitreal injection of a pharmacological agent (separate procedure)
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)
J3299	Injection, triamcinolone acetonide (Xipere), 1 mg
J3300	Injection, triamcinolone acetonide, preservative free, 40 mg (Triesence)
J3301	Injection, triamcinolone acetonide, not otherwise specified (Kenalog)
J3490	Unclassified drugs
J3590	Unclassified biologics
J7311	Fluocinolone acetonide, intravitreal implant 0.01 mg (Retisert)
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg (Ozurdex)
J7313	Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg (Iluvien). Use 19 units of 0.01 dose to bill for the fixed dose of 0.19 mg. Iluvien implant.
J7314	Injection, fluocinolone acetonide, intravitreal implant, 0.18 mg (Yutiq)
J7999	Compounded drug, not otherwise classified
Required Modifiers	
RT	Right side

LT	Left side
50	Bilateral
JW or JZ	Drug waste or no drug waste
Invalid Modifiers	
24	Unrelated Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional During a Postoperative Period
25	Significant, Separately Identifiable Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional on the Same Day of the Procedure or Other Service
26	Professional Component
57	Decision for Surgery
TC	Technical Component
95	Telemedicine

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RELATED POLICIES AND PROCEDURES	
1317	Intravitreal Injections
1347	Jetrea ocriplasmin
1348	Dextenza

DOCUMENT HISTORY		
Approval Date	***Revisions***	***Effective Date***
01/05/2022	Initial policy: content and criteria extracted from policy 1317 as a separate therapeutic category. Added the new drug Dextenza and a new indication. For Ozurdex, removed requirement to have both OCT and FA diagnostic tests.	07/01/2022
07/06/2022	Remove Dextenza (see 1348); no criteria change for other drugs and treatments.	01/01/2023
04/12/2023	Add new drug Xipere plus criteria; add criteria for Triesence; remove all instances of required micron measurements; added retreatment criteria for all drugs.	10/01/2023
09/20/2023	Administrative review for CMS 2024 final rule Medicare Part C equity: no changes.	n/a
01/03/2024	Remove indication of DME for Yutiq administration; add CPT code 67516 for use with Xipere.	05/01/2024
07/10/2024	Remove CPT code 68841, as out of scope. No criteria changes.	10/01/2024

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