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Subject: Corticosteroid Intravitreal Implant

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DESCRIPTION:

Fluocinolone acetonide (Retisert) 0.59 mg implant was FDA-approved in April 2005 for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye. Dexamethasone (Ozurdex) 0.7 mg implant was FDA-approved for macular edema due to branch or central retinal vein occlusion (BRVO/CRVO) in June 2009, for non-infectious posterior uveitis in September 2010, and for diabetic macular edema (DME) in June 2014. Fluocinolone acetonide (Iluvien) 0.19 mg implant was FDA-approved in September 2014 for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Fluocinolone acetonide (Yutiq) 0.18 mg implant was FDA-approved in October 2018 for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Ozurdex was previously granted orphan designation by the FDA in September 1998 for the treatment of non-infectious ocular inflammation of the posterior segment in patients with intermediate, posterior, and panuveitis, and Retisert was previously granted orphan designation status in July 2000 for the treatment uveitis involving the posterior segment of the eye.

Uveitis describes a wide range of conditions characterized by intraocular inflammation. It is a highly heterogeneous condition, varying in etiology, tissues involved, and extent of disease. Uveitis can be either infectious or noninfectious. Noninfectious uveitis is often associated with systemic autoimmune or auto-inflammatory diseases such as ankylosing spondylitis, sarcoidosis, or Behçet's disease; however, most cases have no associated systemic condition. The classification scheme recommended by the Uveitis Study Group and the Standardization of Uveitis Nomenclature (SUN) Working Group is based on anatomic location. Anterior chamber inflammation is categorized as "anterior uveitis", and includes iritis, iridocyclitis, and anterior cyclitis. Inflammation primarily affecting the vitreous is referred to as "intermediate uveitis", and includes pars planitis, posterior cyclitis, and hyalitis. "Posterior uveitis"

describes inflammation of the retina or choroid and accounts for 15% to 30% of diagnoses. Finally, “pan-uveitis” describes the situation where inflammation is seen throughout the anterior chamber, vitreous, and retina or choroid. According to the SUN criteria, disease is further classified according to onset (sudden or insidious), duration (limited or persistent), and course (acute, recurrent, or chronic). Therapy for noninfectious uveitis is aimed at suppressing the immune system, and ranges from topical therapy (e.g., corticosteroid eye drops) to systemic immunosuppression with either high-dose corticosteroids or a wide range of corticosteroid-sparing immunosuppressive medications.

Diabetic macular edema (DME) is the most common cause of visual impairment in patients with diabetes, affecting ~25% of diabetics during their lifetime. It is characterized by swelling of the macula due to gradual leakage of fluids from blood vessels leading to moderate vision loss. Tight glycemic and blood pressure control is first-line treatment to control diabetic retinopathy and DME. First-line medical treatment of DME is usually an intravitreal vascular endothelial growth factor (VEGF) inhibitor. Intravitreal corticosteroid implants are typically reserved for second line use due the high incidence of cataract formation and increases in intraocular pressure (IOP). While there is interest in using a combination of a VEGF inhibitor with a corticosteroid implant, a 2018 phase II RCT assessing the effect of adding dexamethasone implant to continued ranibizumab treatment in patients with persistent DME, demonstrated that there was no improvement in the primary outcome of visual acuity.

In two phase III, randomized, double-blinded trials of patients with diabetic macular edema (n=656), an improvement of at least 15 letters in best corrected visual acuity (BCVA) was achieved in 18% to 21% of those who received dexamethasone intravitreal implant (mean of 4 treatments over 36 months) compared with 10% to 12% who received placebo. In two phase III, randomized, double-blinded trials of patients with macular edema following BRVO or CRVO, dexamethasone-treated patients had significantly greater improvement in BCVA from baseline to 90 days compared with sham-treated patient (29% vs. 11%). In a phase III, randomized, double-blinded trial of patients with noninfectious intermediate or posterior uveitis, a significantly greater percentage of patients receiving intravitreal dexamethasone implant achieved a vitreous haze score of zero (indicating no inflammation) compared with sham-treated patients (47% vs. 12%).

In a phase III, randomized, trial, fluocinolone acetonide 0.59 mg intravitreal implant (Retisert) effectively controlled intraocular inflammation, significantly reducing uveitis recurrence rates in patients with noninfectious posterior uveitis over a 3-year follow-up period. The preimplantation recurrence rate of 62% for the 0.59-mg implant group dropped to 4%, 10%, and 20% in years 1, 2, and 3, respectively, following implantation. However, there were significant increased incidents of intraocular hypertension and cataract formation. An increase in IOP was seen at week 4 (approximately 6 mm Hg) compared with no significant change in the non-implanted eyes. Cataracts severe enough to require surgery were more commonly seen in implanted eyes vs. non-implanted eyes (9.9% vs 2.7%).

The efficacy and safety of fluocinolone acetonide 0.18 mg intravitreal implant (Yutiq) was assessed in two randomized phase III trials that enrolled patients with non-infectious uveitis affecting the posterior segment of the eye. The primary efficacy endpoint in both trials was the proportion of patients who experienced a recurrence of uveitis in the study eye within 6 months of follow-up; recurrence was also assessed at 12 months. Recurrence of uveitis was defined as either deterioration in visual acuity, vitreous haze attributable to non-infectious uveitis or the need for rescue medications. In Study 1 (n=129), recurrence at 6 and 12 months was 18% vs. 79% (Yutiq vs. sham injection) and 25% vs. 80%,

respectively. In Study 2 (n=153), recurrence at 6 and 12 months was 22% vs. 54% and 33% vs. 60%, respectively.

Two identical phase III randomized, double-blinded, sham injection-controlled trials known as the FAME studies (FAME A and FAME B) were conducted for over 36 months to study the efficacy and safety of intravitreal inserts releasing 0.2 mcg/day (low dose) or 0.5 mcg/day (high dose) fluocinolone acetonide in patients with DME. The manufacturer submission only considered the 0.2 mcg/day of fluocinolone. The percentage of patients who gained 15 letters or more using the last observation carried forward was 28.7% (low dose) and 27.8% (high dose) compared with 18.9% in the sham group. Cataract surgery was performed in 80% of phakic patients in the low-dose group and 87.2% of the high-dose group vs. 27.3% of the sham group. The occurrence of laser or incisional glaucoma surgery by 36 months was 6.1% in the low-dose group and 10.6% in the high-dose group vs. 0.5% of the sham group.

POSITION STATEMENT:

Ozurdex

Initiation of dexamethasone (Ozurdex) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "4"):

1. The indication for use is **ANY** of the following ("a", "b", or "c"):
    a. Chronic, non-infectious uveitis affecting the posterior segment of the eye (i.e., intermediate uveitis, posterior uveitis, or panuveitis)
    b. Diabetic macular edema (DME)
    c. Branch or central retinal vein occlusion (BRVO/CRVO)
2. Member will **NOT** receive **ANY** of the following medications concurrently with Ozurdex in the same eye:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Dexamethasone (Dextenza) ophthalmic insert
    d. Fluocinolone acetonide (Iluvien, Retisert, and Yutiq) intravitreal implant
    e. Pegaptanib (Macugen)
    f. Ranibizumab (Lucentis)
3. Member does **NOT** have an active or suspected ocular or periocular infection
4. The dosage does not exceed one 0.7 mg implant per treated eye and it is not implanted more often than every 3 months (i.e., maximum of 4 implants per 12 months).

Approval duration: 1 year

Continuation of dexamethasone (Ozurdex) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "5"):

1. An authorization or reauthorization for Ozurdex has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of chronic non-infectious uveitis, DME, or BRVO/CRVO (if another health plan, documentation of a health plan-paid claim for Ozurdex during the 2 years before the authorization request must be submitted), **OR** the member has previously met **ALL** indication-specific initiation criteria
2. Member has had a beneficial response to treatment with Ozurdex
3. Member will **NOT** receive **ANY** of the following medications concurrently with Ozurdex in the same eye:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Dexamethasone (Dextenza) ophthalmic insert
    d. Fluocinolone acetonide (Iluvien, Retisert, and Yutiq) intravitreal implant
    e. Pegaptanib (Macugen)
    f. Ranibizumab (Lucentis)
4. Member does **NOT** have an active or suspected ocular or periocular infection
5. The dosage does not exceed one 0.7 mg implant per treated eye, and it is not implanted more often than every 3 months (i.e., maximum of 4 implants per 12 months)

Approval duration: 1 year

Iluvien

Initiation of fluocinolone acetonide (Iluvien) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "5"):

1. Member has a diagnosis of diabetic macular edema (DME)
2. Member has been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP)
3. Member will **NOT** receive **ANY** of the following medications concurrently with Iluvien in the same eye as continuous maintenance therapy*:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    a. Dexamethasone (Ozurdex) intravitreal implant or dexamethasone (Dextenza) ophthalmic insert
    c. Fluocinolone acetonide (Retisert, Yutiq) intravitreal implant
    d. Pegaptanib (Macugen)
    e. Ranibizumab (Lucentis)

    **Beovu, Eylea, Lucentis, or Macugen may be used as periodic rescue therapy for breakthrough symptoms*
4. Member does **NOT** have an active or suspected ocular or periocular infection

5. The dosage does not exceed one 0.19 mg implant per treated eye, and it is not implanted more often than every 34 months.

Approval duration: Single implant per treated eye within 2 months of approval.

Continuation of fluocinolone acetonide (Iluvien) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for Iluvien has been previously approved by Florida Blue or another health plan in the past 4 years for the treatment of DME (if another health plan, documentation of a health plan-paid claim for Iluvien during the 4 years before the authorization request must be submitted), **OR** the member has previously met **ALL** indication-specific initiation criteria
2. Member has had a beneficial response to treatment with Iluvien
3. Member will **NOT** receive **ANY** of the following medications concurrently with Iluvien in the same eye as continuous maintenance therapy*:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Dexamethasone (Ozurdex) intravitreal implant or dexamethasone (Dextenza) ophthalmic insert
    d. Fluocinolone acetonide (Retisert, Yutiq) intravitreal implant
    e. Pegaptanib (Macugen)
    f. Ranibizumab (Lucentis)

    **Beovu, Eylea, Lucentis, or Macugen may be used as periodic rescue therapy for breakthrough symptoms*
4. Member does **NOT** have an active or suspected ocular or periocular infection
5. Treatment will **NOT** occur sooner than 34 months after the prior Iluvien implant
6. The dosage does not exceed one 0.19 mg implant per treated eye, and it is not implanted more often than every 34 months

Approval duration: Single implant per treated eye within 2 months of approval

Retisert

Initiation of fluocinolone acetonide (Retisert) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. Member has a diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye (i.e., intermediate uveitis, posterior uveitis, or panuveitis)
2. Member has had an inadequate response (i.e., recurrent or unresolved uveitis) to fluocinolone acetonide 0.18 mg implant (Yutiq)

3. For members with bilateral disease only (i.e., both eyes effected): member has had an inadequate response to least **ONE** or contraindications to **ALL** of the following oral immunosuppressive agents (the contraindications must be specified):
    - Azathioprine
    - Cyclosporine
    - Methotrexate
    - Mycophenolate mofetil
    - Tacrolimus
4. Member will **NOT** receive **ANY** of the following medications concurrently with Retisert in the same eye:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Fluocinolone acetonide (Iluvien, Yutiq) intravitreal implant
    d. Dexamethasone intravitreal implant (Ozurdex) or dexamethasone ophthalmic insert (Dextenza)
    e. Pegaptanib (Macugen)
    f. Ranibizumab (Lucentis)
5. Member does **NOT** have an active or suspected ocular or periocular infection
6. The dosage does not exceed one 0.59 mg implant per treated eye, and it is not implanted more often than every 28 months.

Approval duration: Single implant per treated eye within 2 months of approval.

Continuation of fluocinolone acetonide (Retisert) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for Retisert has been previously approved by Florida Blue or another health plan in the past 4 years for the treatment of chronic, non-infectious uveitis (if another health plan, documentation of a health plan-paid claim for Retisert during the 4 years before the authorization request must be submitted), **OR** the member has previously met **ALL** indication-specific initiation criteria
2. Member has had a beneficial response to treatment with Retisert
3. Member will **NOT** receive ANY of the following medications concurrently with Retisert in the same eye:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Fluocinolone acetonide (Iluvien, Yutiq) intravitreal implant
    d. Dexamethasone intravitreal implant (Ozurdex) or dexamethasone ophthalmic insert (Dextenza)
    e. Pegaptanib (Macugen)

f. Ranibizumab (Lucentis)

4. Member does **NOT** have an active or suspected ocular or periocular infection
5. Treatment will **NOT** occur sooner than 28 months after the prior Retisert implant
6. The dosage does not exceed one 0.59 mg implant per treated eye, and it is not implanted more often than every 28 months.

Approval duration: Single implant per treated eye within 2 months of approval

Yutiq

Initiation of fluocinolone acetonide (Yutiq) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "5"):

1. Member has a diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye (i.e., intermediate uveitis, posterior uveitis, or panuveitis)
2. For members with bilateral disease only (i.e., both eyes effected): member has had an inadequate response to least **ONE** or contraindications to **ALL** of the following oral immunosuppressive agents (the contraindications must be specified):
    - Azathioprine
    - Cyclosporine
    - Methotrexate
    - Mycophenolate mofetil
    - Tacrolimus
3. Member will **NOT** receive **ANY** of the following medications concurrently with Yutiq in the same eye:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Fluocinolone acetonide (Iluvien, Retisert) intravitreal implant
    d. Dexamethasone intravitreal implant (Ozurdex) or dexamethasone ophthalmic insert (Dextenza)
    e. Pegaptanib (Macugen)
    f. Ranibizumab (Lucentis)
4. Member does **NOT** have an active or suspected ocular or periocular infection
5. The dosage does not exceed one 0.18 mg implant per treated eye, and it is not implanted more often than every 34 months.

Approval duration: Single implant per treated eye within 2 months of approval.

Continuation of fluocinolone acetonide (Yutiq) implant **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for Yutiq has been previously approved by Florida Blue or another health plan in the past 4 years for the treatment of chronic, non-infectious uveitis (if another health plan, documentation of a health-plan paid claim for Yutiq during the 4 years before the authorization request must be submitted), **OR** the member has previously met **ALL** indication-specific initiation criteria
2. Member has had a beneficial response to treatment with Yutiq
3. Member will **NOT** receive **ANY** of the following medications concurrently with Yutiq in the same eye:
    a. Aflibercept (Eylea)
    b. Brolucizumab (Beovu)
    c. Fluocinolone acetonide (Iluvien, Retisert) intravitreal implant
    d. Dexamethasone intravitreal implant (Ozurdex) or dexamethasone ophthalmic insert (Dextenza)
    e. Pegaptanib (Macugen)
    f. Ranibizumab (Lucentis)
4. Member does **NOT** have an active or suspected ocular or periocular infection
5. Treatment will **NOT** occur sooner than 34 months after the prior Yutiq implant
6. The dosage does not exceed one 0.18 mg implant per treated eye, and it is not implanted more often than every 34 months

Approval duration: Single implant per treated eye within 2 months of approval

Fluocinolone acetonide intravitreal implant 0.59 mg (Retisert), 0.19 mg (Iluvien), or 0.18 mg (Yutiq); and dexamethasone intravitreal implant 0.7 mg (Ozurdex) are considered investigational for the treatment of:

- Birdshot retinochoroidopathy
- Cystoid macular edema related to retinitis pigmentosa
- Idiopathic macular telangiectasia type 1
- Postoperative macular edema
- Circumscribed choroidal hemangiomas
- Proliferative vitreoretinopathy
- Radiation retinopathy

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

Ozurdex

FDA-approval: indicated 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
- diabetic macular edema (DME)

How supplied: a rod-shaped intravitreal implant containing 0.7 mg dexamethasone in the NOVADUR® solid polymer sustained-release drug delivery system. It is preloaded into a single-use plastic applicator supplied in a foil pouch.

Iluvien

FDA-approval: indicated 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.

How supplied: a non-bioerodable intravitreal implant in a drug delivery system containing 0.19 mg fluocinolone acetonide supplied in a sterile single use preloaded applicator with a 25-gauge needle, packaged in a tray sealed with a lid inside a carton. The implant is designed to release fluocinolone acetonide at an initial rate of 0.25 mcg/day and lasting 36 months.

Retisert

FDA-approval: indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. The implant is designed to release fluocinolone acetonide at a nominal initial rate of 0.6 mcg/day, decreasing over the first month to a steady state between 0.3 to 0.4 mcg/day over approximately 30 months. Following depletion as evidenced by recurrence of uveitis, the implant may be replaced.

How supplied: a tablet encased in a silicone elastomer cup containing a release orifice and a polyvinyl alcohol membrane positioned between the tablet and the orifice. The silicone elastomer cup assembly is attached to a silicone elastomer suture tab with silicone adhesive. Each implant is approximately 3 mm x 2 mm x 5 mm. Each implant is stored in a clear polycarbonate case within a foil pouch within a Tyvek peelable overwrap.

Yutiq

FDA-approval: indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye

How supplied: a sterile non-bioerodible intravitreal implant containing 0.18 mg fluocinolone acetonide in a 36-month sustained-release drug delivery system. It is designed to release fluocinolone acetonide at an initial rate of 0.25 mcg/day. Product is supplied in a sterile single-dose preloaded applicator with a 25-gauge needle, packaged in a sealed sterile foil pouch inside a sealed Tyvek pouch inside a carton box.

PRECAUTIONS:

Ozurdex

Contraindications

- Active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- Glaucoma patients who have cup to disc ratios of greater than 0.8.
- Torn or ruptured posterior lens capsule (risk of migration into the anterior chamber). Laser posterior capsulotomy in pseudophakic patients is **NOT** a contraindication.
- Known hypersensitivity to any components of this product.

Warnings

- **Intravitreal injection-related effects**: Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection.
- **Steroid-related effects**: Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

Iluvien

Contraindications

- Active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- Glaucoma patients who have cup to disc ratios of greater than 0.8.
- Known hypersensitivity to any components of this product.

Warnings

- **Intravitreal injection-related effects**: Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection.
- **Steroid-related effects**: Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- **Risk of implant migration**: The implant may migrate into the anterior chamber if the posterior lens capsule is not intact.

Retisert

Contraindications

- Active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in active bacterial, mycobacterial or fungal infections of the eye.

Warnings

- **Cataract formation**: Nearly all phakic patients are expected to develop cataracts and require cataract surgery.
- **Endophthalmitis**: Late onset endophthalmitis has been observed. Nearly all patients will experience an immediate and temporary decrease in visual acuity in the implanted eye which lasts for approximately one to four weeks post-operatively.
- **Increase in intraocular pressure**: Use of corticosteroids may result in elevated IOP and/or glaucoma. IOP lowering medications were required in >75% of patients; filtering surgeries were required in >35% of patients.
- **Separation of implant components**: Physicians should periodically monitor the integrity of the implant by visual inspection.

Yutiq

Contraindications

- Patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- Patients with known hypersensitivity to any components of this product.

Warnings

- **Intravitreal Injection-related Effects**: Intravitreal injections, including those with Yutiq, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection.
- **Steroid-related Effects**: Use of corticosteroids, including Yutiq may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- **Risk of Implant Migration**: Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding: Ozurdex

J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg

HCPCS Coding: Iluvien

J7313	Injection, fluocinolone acetonide, intravitreal implant (Iluvien), 0.01 mg

HCPCS Coding: Retisert

J7311	Fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg

HCPCS Coding: Yutiq

J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg

ICD-10 Diagnosis Codes: Ozurdex

E08.311	Diabetes mellitus due to underlying condition with unspecified 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
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211 – E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E09.3311 – E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E09.3411 – E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E09.3511 – E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E09.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema

E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.3211 – E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13.3311 – E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13.3411 – E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.3511 – E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema
H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
H30.001	Unspecified focal chorioretinal inflammation, right eye
H30.002	Unspecified focal chorioretinal inflammation, left eye
H30.003	Unspecified focal chorioretinal inflammation, bilateral
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye
H30.021	Focal chorioretinal inflammation of posterior pole, right eye
H30.022	Focal chorioretinal inflammation of posterior pole, left eye
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye
H30.031	Focal chorioretinal inflammation, peripheral, right eye
H30.032	Focal chorioretinal inflammation, peripheral, left eye
H30.033	Focal chorioretinal inflammation, peripheral, bilateral
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral

H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.101	Unspecified disseminated chorioretinal inflammation, right eye
H30.102	Unspecified disseminated chorioretinal inflammation, left eye
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral
H30.109	Unspecified disseminated chorioretinal inflammation, unspecified eye
H30.111	Disseminated chorioretinal inflammation of posterior pole, right eye
H30.112	Disseminated chorioretinal inflammation of posterior pole, left eye
H30.113	Disseminated chorioretinal inflammation of posterior pole, bilateral
H30.119	Disseminated chorioretinal inflammation of posterior pole, unspecified eye
H30.121	Disseminated chorioretinal inflammation, peripheral, right eye
H30.122	Disseminated chorioretinal inflammation, peripheral, left eye
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral
H30.129	Disseminated chorioretinal inflammation, peripheral, unspecified eye
H30.131	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye
H30.20	Posterior cyclitis, unspecified eye
H30.21	Posterior cyclitis, right eye
H30.22	Posterior cyclitis, left eye
H30.23	Posterior cyclitis, bilateral
H30.891	Other chorioretinal inflammations, right eye
H30.892	Other chorioretinal inflammations, left eye
H30.893	Other chorioretinal inflammations, bilateral
H30.899	Other chorioretinal inflammations, unspecified eye
H30.90	Unspecified chorioretinal inflammation, unspecified eye
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral
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
H44.111	Panuveitis, right eye
H44.112	Panuveitis, left eye
H44.113	Panuveitis, bilateral
H44.119	Panuveitis, unspecified eye

ICD-10 Diagnosis Codes: Iluvien

E08.311	Diabetes mellitus due to underlying condition with unspecified 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
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211 – E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E09.3311 – E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E09.3411 – E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E09.3511 – E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema

E13.3211 – E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13.3311 – E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13.3411 – E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.3511 – E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema

ICD-10 Diagnoses Codes: Retisert

H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
H30.001	Unspecified focal chorioretinal inflammation, right eye
H30.002	Unspecified focal chorioretinal inflammation, left eye
H30.003	Unspecified focal chorioretinal inflammation, bilateral
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye
H30.021	Focal chorioretinal inflammation of posterior pole, right eye
H30.022	Focal chorioretinal inflammation of posterior pole, left eye
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye
H30.031	Focal chorioretinal inflammation, peripheral, right eye
H30.032	Focal chorioretinal inflammation, peripheral, left eye
H30.033	Focal chorioretinal inflammation, peripheral, bilateral
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral
H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.101	Unspecified disseminated chorioretinal inflammation, right eye
H30.102	Unspecified disseminated chorioretinal inflammation, left eye
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral
H30.109	Unspecified disseminated chorioretinal inflammation, unspecified eye
H30.111	Disseminated chorioretinal inflammation of posterior pole, right eye
H30.112	Disseminated chorioretinal inflammation of posterior pole, left eye
H30.113	Disseminated chorioretinal inflammation of posterior pole, bilateral
H30.119	Disseminated chorioretinal inflammation of posterior pole, unspecified eye
H30.121	Disseminated chorioretinal inflammation, peripheral, right eye

H30.122	Disseminated chorioretinal inflammation, peripheral, left eye
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral
H30.129	Disseminated chorioretinal inflammation, peripheral, unspecified eye
H30.131	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye
H30.20	Posterior cyclitis, unspecified eye
H30.21	Posterior cyclitis, right eye
H30.22	Posterior cyclitis, left eye
H30.23	Posterior cyclitis, bilateral
H30.891	Other chorioretinal inflammations, right eye
H30.892	Other chorioretinal inflammations, left eye
H30.893	Other chorioretinal inflammations, bilateral
H30.899	Other chorioretinal inflammations, unspecified eye
H30.90	Unspecified chorioretinal inflammation, unspecified eye
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral
H44.111	Panuveitis, right eye
H44.112	Panuveitis, left eye
H44.113	Panuveitis, bilateral
H44.119	Panuveitis, unspecified eye

ICD-10 Diagnosis Codes: Yutiq

H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
H30.001	Unspecified focal chorioretinal inflammation, right eye
H30.002	Unspecified focal chorioretinal inflammation, left eye
H30.003	Unspecified focal chorioretinal inflammation, bilateral
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye
H30.021	Focal chorioretinal inflammation of posterior pole, right eye
H30.022	Focal chorioretinal inflammation of posterior pole, left eye
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye
H30.031	Focal chorioretinal inflammation, peripheral, right eye
H30.032	Focal chorioretinal inflammation, peripheral, left eye

H30.033	Focal chorioretinal inflammation, peripheral, bilateral
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral
H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.101	Unspecified disseminated chorioretinal inflammation, right eye
H30.102	Unspecified disseminated chorioretinal inflammation, left eye
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral
H30.109	Unspecified disseminated chorioretinal inflammation, unspecified eye
H30.111	Disseminated chorioretinal inflammation of posterior pole, right eye
H30.112	Disseminated chorioretinal inflammation of posterior pole, left eye
H30.113	Disseminated chorioretinal inflammation of posterior pole, bilateral
H30.119	Disseminated chorioretinal inflammation of posterior pole, unspecified eye
H30.121	Disseminated chorioretinal inflammation, peripheral, right eye
H30.122	Disseminated chorioretinal inflammation, peripheral, left eye
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral
H30.129	Disseminated chorioretinal inflammation, peripheral, unspecified eye
H30.131	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye
H30.20	Posterior cyclitis, unspecified eye
H30.21	Posterior cyclitis, right eye
H30.22	Posterior cyclitis, left eye
H30.23	Posterior cyclitis, bilateral
H30.891	Other chorioretinal inflammations, right eye
H30.892	Other chorioretinal inflammations, left eye
H30.893	Other chorioretinal inflammations, bilateral
H30.899	Other chorioretinal inflammations, unspecified eye
H30.90	Unspecified chorioretinal inflammation, unspecified eye
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral
H44.111	Panuveitis, right eye
H44.112	Panuveitis, left eye
H44.113	Panuveitis, bilateral
H44.119	Panuveitis, unspecified eye

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: No National Coverage Determination (NCD) or Local Coverage Determination (LCD) was found at the time of the last guideline review date.

DEFINITIONS:

Anterior uveitis - inflammation occurring in the front of the eye (anterior chamber) which includes the iris and adjacent tissue known as the ciliary body. This diagnosis includes iritis, iridocyclitis, and anterior cyclitis. Generally, less severe than other forms of uveitis.

Chronic uveitis – persistent uveitis (>3 months duration) with a relapse in less than 3 months after discontinuation of treatment.

Intermediate uveitis – inflammation occurring in the center of eye which is the vitreous. This diagnosis includes pars planitis, posterior cyclitis, and hyalitis.

Macular edema - swelling of the retina due to leaking of fluid from blood vessels within the macula (the central portion of the retina). Diabetic macular edema (DME) is macular edema that occurs in patients with diabetes.

Pan-uveitis – inflammation occurring throughout the eye including the anterior chamber, vitreous, and retina or choroid. This diagnosis includes diffuse uveitis and endophthalmitis.

Posterior uveitis - inflammation occurring in the back of the eye which includes the retina or choroid and accounts for 15% to 30% of diagnoses. This diagnosis includes retinitis, neuroretinitis, retinochoroiditis, chorioretinitis, choroiditis (focal, multifocal, or diffuse), and papillitis.

Retinal vein occlusion - a blockage of one or more veins that carry blood away from the retina. Central retinal vein occlusion (CRVO) occurs when the blockage is in the main vein in the retina. Branch retinal vein occlusion (BRVO) occurs when the blockage is one of the smaller veins attached to the main vein in the retina.

RELATED GUIDELINES:

Vascular Endothelial Growth Factor Inhibitors for Ocular Neovascularization, 09-J1000-78

OTHER:

None

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 9/11/24.

GUIDELINE UPDATE INFORMATION:

05/15/15	New Medical Coverage Guideline.
08/15/15	Revision consisting of update to the position statement.
11/01/15	Revision: ICD-9 Codes deleted.
01/01/16	Annual HCPCS coding update: added code J7313 and deleted codes C9450 and J3490.
02/15/16	Revision consisting of update to the position statement and new references.
05/15/16	Review and revision of guideline consisting of references.
10/01/16	Revision: ICD-10 code updates
05/15/17	Review and revision to guideline consisting of updating the description section, position statement, and references.
05/15/18	Review and revision to guideline consisting of updating the description section and references.
03/15/19	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, billing/coding, and references based on the FDA approval of Yutiq.
05/15/19	Review and revision to guideline consisting of updating the references.
10/01/19	Revision: Updated descriptions for HCPCS J7311 and J7313. Added HCPCS J7314 and removed C9399 and J3490.
01/01/20	Revision to guideline consisting of updating the position statement.
05/15/20	Review and revision to guideline consisting of updating the position statement and references.
09/15/20	Revision to guideline consisting of updating the position statement and references.
10/15/21	Review and revision to guideline consisting of updating the position statement and references.
01/15/23	Updated position statement and references.
10/15/23	Review and revision to guideline consisting of updating the references.

10/15/24	Review and revision to guideline consisting of updating the references.