MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Intravitreal and Punctum Corticosteroid Implants

Table of Contents

Policy Number: 272

BCBSA Reference Number: 9.03.23 (For Plan internal use only)
NDC/LCD: N/A

Related Policies

Aqueous Shunts and Stents for Glaucoma, #223

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

A fluocinolone acetonide intravitreal implant 0.59 mg (Retisert) may be **MEDICALLY NECESSARY** for the treatment of:

- Chronic noninfectious intermediate, posterior, or panuveitis.

A fluocinolone acetonide intravitreal implant 0.18mg (Yutiq) may be **MEDICALLY NECESSARY** for the treatment of:

- Chronic noninfectious uveitis affecting the posterior segment of the eye in individuals who are contraindicated or unable to tolerate standard medical therapy.[1]

A fluocinolone acetonide intravitreal implant 0.19 mg (Iluvien) may be considered **MEDICALLY NECESSARY** for the treatment of:

- Diabetic macular edema in individuals who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

A dexamethasone intravitreal implant 0.7 mg (Ozurdex) may be **MEDICALLY NECESSARY** for the treatment of:

- Non-infectious ocular inflammation, or uveitis, affecting the intermediate or posterior segment of the eye, **OR**
- Macular edema following branch or central retinal vein occlusion, **OR**
- Diabetic macular edema.

A punctum dexamethasone insert 0.4 mg (Dextenza) may be considered **MEDICALLY NECESSARY** for the treatment of:

- Ocular inflammation and pain following ophthalmic surgery.

A punctum dexamethasone insert 0.4 mg (Dextenza) is considered **INVESTIGATIONAL** for:

- Ocular itching associated with allergic conjunctivitis.

A fluocinolone acetonide intravitreal implant 0.59 mg (Retisert) or 0.19 mg (Iluvien) or dexamethasone intravitreal implant 0.7 mg (Ozurdex) is 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
- Prophylaxis of cystoid macular edema in individuals with noninfectious intermediate uveitis or posterior uveitis and cataract undergoing cataract surgery.

A fluocinolone acetonide intravitreal implant 0.18 mg (Yutiq) is considered **INVESTIGATIONAL** for all other conditions.

All other uses of a corticosteroid intravitreal or punctum implant are considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT Codes	Description
67027	Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous
67028	Intravitreal injection of a pharmacologic agent (separate procedure)

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
J7311	Injection, fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg
J7313	Injection, fluocinolone acetonide, intravitreal implant (iluvien), 0.01 mg

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.3211	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye
E08.3212	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye
E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3311	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E08.3312	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3411	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye
E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye
E08.3512	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye

E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral
E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3511	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E09.3512	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye

E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye

E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
H05.00	Unspecified acute inflammation of orbit
H05.10	Unspecified chronic inflammatory disorders of orbit
H20.9	Unspecified iridocyclitis
H30.001	Unspecified focal chorioretinal inflammation, right eye
H30.002	Unspecified focal chorioretinal inflammation, left eye
H30.003	Unspecified focal chorioretinal inflammation, bilateral
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral
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
H30.041	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
H30.101	Unspecified disseminated chorioretinal inflammation, right eye
H30.102	Unspecified disseminated chorioretinal inflammation, left eye
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral
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
H30.141	Acute posterior multifocal placoid pigment epitheliopathy, right eye

H30.142	Acute posterior multifocal placoid pigment epitheliopathy, left eye
H30.143	Acute posterior multifocal placoid pigment epitheliopathy, bilateral
H30.21	Posterior cyclitis, right eye
H30.22	Posterior cyclitis, left eye
H30.23	Posterior cyclitis, bilateral
H30.811	Harada's disease, right eye
H30.812	Harada's disease, left eye
H30.813	Harada's disease, 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
H34.8310	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
H34.9	Unspecified retinal vascular occlusion
H35.81	Retinal edema
H44.111	Panuveitis, right eye
H44.112	Panuveitis, left eye
H44.113	Panuveitis, bilateral
H44.119	Panuveitis, unspecified eye

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS code above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
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
H30.111	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

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg

CPT Codes

CPT codes:	Code Description
0356T	Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each

HCPCS Codes

HCPCS codes:	Code Description
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg

Description

Eye Conditions

Uveitis

Uveitis encompasses various conditions, of infectious and 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. Noninfectious etiologies include sarcoidosis, Behçet syndrome, and “white dot” syndromes such as multifocal choroiditis or “birdshot” chorioretinopathy. Uveitis may be idiopathic, have a sudden or insidious onset, a duration that is limited (<3 months) or persistent, and a course that may be acute, recurrent, or chronic.

The classification scheme recommended by the Uveitis Study Group and the Standardization of Uveitis Nomenclature Working Group is based on anatomic location. Patients with anterior uveitis typically develop symptoms such as light sensitivity, pain, tearing, and redness of the sclera. In posterior uveitis, which comprises approximately 5% to 38% of all uveitis cases in the United States, the primary site of inflammation is in the choroid or retina (or both). Patients with intermediate or posterior uveitis typically experience minimal pain, decreased visual acuity, and the presence of floaters (bits of vitreous debris or cells that cast shadows on the retina). Chronic inflammation associated with posterior segment uveitis can lead to cataracts, glaucoma, and structural damage to the eye, resulting in severe and permanent vision loss.

Treatment

The primary goal of therapy for uveitis is to preserve vision. Noninfectious uveitis typically responds well to corticosteroid treatment. Immunosuppressive therapy (eg, antimetabolites, alkylating agents, T-cell inhibitors, tumor necrosis factor inhibitors) may also be used to control severe uveitis. Immunosuppressive therapy is typically reserved for patients who require chronic high-dose systemic steroids to control their disease. While effective, immunosuppressants may have serious and potentially life-threatening adverse effects, including renal and hepatic failure and bone marrow suppression.

Macular Edema After Retinal Vein Occlusion

Retinal vein occlusions are classified by whether the central retinal vein or one of its branches is obstructed. Central retinal vein occlusion and branch retinal vein occlusion differ in pathophysiology, clinical course, and therapy. Central retinal vein occlusions are categorized as ischemic or nonischemic. Ischemic central retinal vein occlusions are referred to as severe, complete, or total vein obstruction, and account for 20%

to 25% of all central retinal vein occlusions. Macular edema and permanent macular dysfunction occur in virtually all patients with ischemic central retinal vein occlusion, and in many patients with nonischemic central retinal vein occlusion. Branch retinal vein occlusion is a common retinal vascular disorder in adults between 60 and 70 years of age and occurs approximately 3 times more often than central retinal vein occlusion.

Treatment
Intravitreal injections of triamcinolone are used to treat macular edema associated with central retinal vein occlusion, with a modest beneficial effect on visual acuity. The treatment effect lasts about 6 months, and repeat injections may be necessary. Cataracts are a common side effect, and steroid-related pressure elevation occurs in about one-third of patients, with 1% requiring filtration surgery.
Macular photocoagulation with grid laser improves vision in branch retinal vein occlusion but is not recommended for central retinal vein occlusion. Although intravitreal injections of triamcinolone have also been used for branch retinal vein occlusion, serious adverse events have stimulated the evaluation of new treatments, including intravitreal steroid implants or the intravitreal injection of antivascular endothelial growth factor.

Diabetic Macular Edema
Diabetic retinopathy is a common microvascular complication of diabetes and a leading cause of blindness in adults. The 2 most serious complications for vision are diabetic macular edema and proliferative diabetic retinopathy. At its earliest stage (nonproliferative retinopathy), microaneurysms occur. As the disease progresses, blood vessels that nourish 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. Diabetic macular edema 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 (macular edema) during the proliferative or nonproliferative stages of the disease. Although the proliferative disease is the main blinding complication of diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

Treatment
Tight glycemic and blood pressure control is the first line of treatment to control diabetic retinopathy, followed by laser photocoagulation for patients 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. Alternatives to intravitreal implants include intravitreal injection of triamcinolone acetonide, which is used as off-label adjunctive therapy for diabetic macular edema. Angiostatic agents such as injectable vascular endothelial growth factor inhibitors, which block stages in the pathway leading to new blood vessel formation (angiogenesis), have demonstrated efficacy in diabetic macular edema.

Age-Related Macular Degeneration
Age-related macular degeneration is a degenerative disease of the retina that results in loss of central vision with increasing age. Two different forms of degeneration, known as dry and wet, may be observed. The dry form (also known as atrophic or areolar) is more common and is often a precursor to the wet form (also known as exudative neovascular or disciform). The wet form is more devastating and characterized by serous or hemorrhagic detachment of the retinal pigment epithelium and the development of choroidal neovascularization, which greatly increases the risk of developing severe irreversible loss of vision. Choroidal neovascularization is categorized as classic or occult.

Treatment
Effective specific therapies for exudative or wet age-related macular degeneration are an intravitreous injection of a vascular endothelial growth factor inhibitor, possibly thermal laser photocoagulation (in selected patients), and photodynamic therapy.

Intravitreal and Punctum Implants

Intravitreal and punctum implants deliver a continuous concentration of a pharmacologic agent to the eye over a prolonged period. The goal of therapy is to reduce inflammation in the eye while minimizing the adverse events of the therapeutic regimen.

Selection of the route of corticosteroid administration (topical, systemic, periocular, or intraocular injection) is based on the cause, location, and severity of the disease. Each therapeutic approach has drawbacks. For example, topical corticosteroids require frequent (eg, hourly) administration and may not adequately penetrate the posterior segment of the eye due to their poor ability to penetrate ocular tissues. Systemically administered drugs penetrate poorly into the eye because of the blood-retinal barrier, and high-dose or long-term treatments may be necessary. Long-term systemic therapies can be associated with substantial adverse events such as hypertension and osteoporosis, while repeated (every 4 to 6 weeks) intraocular corticosteroid injections may result in pain, intraocular infection, globe perforation, fibrosis of the extraocular muscles, reactions to the delivery vehicle, increased intraocular pressure, and cataract development.

Corticosteroid implants are biodegradable or nonbiodegradable. Nonbiodegradable systems are thought to be preferable for treating chronic, long-term disease, while biodegradable products may be preferred for conditions that require short-term therapy. Although the continuous local release of steroid with an implant may reduce or eliminate the need for intravitreal injections and/or long-term systemic therapy, insertion or surgical implantation of the device carries risks, and the device could increase ocular toxicity due to increased corticosteroid concentrations in the eye over a longer duration. With any route of administration, cataracts are a frequent complication of long-term corticosteroid therapy.

Intraocular corticosteroid implants being evaluated include the following:

- Retisert (nonbiodegradable fluocinolone acetonide intravitreal implant; Bausch & Lomb) is a sterile implant that consists of a tablet containing fluocinolone acetonide 0.59 mg, a synthetic corticosteroid that is less soluble in aqueous solution than dexamethasone. The tablet is encased in a silicone elastomer cup with a release orifice and membrane; the entire elastomer cup assembly is attached to a suture tab. Following implantation (via pars plana incision and suturing) in the vitreous, the implant releases the active drug at a rate of 0.3 to 0.4 µg/d over 2.5 years.
- Iluvien (nonbiodegradable injectable intravitreal implant with fluocinolone acetonide; Alimera Sciences) is a rod-shaped device made of polyimide and polyvinyl alcohol. It is small enough to be placed using a 25-gauge applicator. It is expected to provide sustained delivery of fluocinolone acetonide for up to 3 years.
- Ozurdex (previously known as Posurdex; biodegradable dexamethasone intravitreal implant; Allergan) is composed of a biodegradable copolymer of lactic acid and glycolic acid with micronized dexamethasone. This implant is placed into the vitreous cavity through the pars plana using a customized, single-use, 22-gauge applicator. The implant provides intravitreal dexamethasone for up to 6 months. The mean number of Ozurdex injections reported in the literature is 4.2 injections per year, and more than 6 consecutive injections have been reported.[1,2,]
- Dextenza (biodegradable dexamethasone intracanalicular insert; Ocular Therapeutix) is a rod-shaped hydrogel device that is designed to deliver a sustained and tapered release of 0.4 mg of dexamethasone over 4 weeks. Following ophthalmic surgery, it is inserted through the inferior punctum into the canaliculus of the operative eye. To allow for visualization and retention monitoring, the hydrogel device is conjugated with fluorescein. No removal is required as the device is designed to resorb and exit the nasolacrimal system independently.
- Yutiq (nonbiodegradable fluocinolone acetonide intravitreal implant; EyePoint Pharmaceuticals U.S., Inc.) is a sterile 3.3 mm-long implant consisting of fluocinolone acetonide 0.18 mg that is preloaded into a single-dose applicator and injected directly into the vitreous. It is designed to provide a sustained release of fluocinolone acetonide at an initial rate of 0.25 mcg/day over a 36-month period.

Summary

Description

An intravitreal implant is a drug delivery system, injected or surgically implanted in the vitreous of the eye, for sustained release of a pharmacologic agent to the posterior and intermediate segments of the eye. Four intravitreal corticosteroid implants, ie, fluocinolone acetonide 0.59 mg (Retisert), fluocinolone acetonide

0.19 mg (Iluvien), fluocinolone acetonide 0.18 mg (Yutiq), and dexamethasone 0.7 mg (Ozurdex) are reviewed herein. Fluocinolone acetonide implants are nonerodible and deliver drug up to 30 to 36 months while dexamethasone implants are bioerodible and last up to 6 months.

A punctum implant is a drug delivery device that is inserted through the lower lacrimal punctum into the canaliculus, for sustained release of a pharmacologic agent to the ocular surface. Dexamethasone ophthalmic insert 0.4 mg (Dextenza) is the first corticosteroid intracanalicular insert and is reviewed herein.

Summary of Evidence

Uveitis

For individuals with chronic noninfectious intermediate or posterior uveitis who receive an intravitreal fluocinolone acetonide implant (0.59 mg), the evidence includes 4 randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Two of the 4 RCTs compared 2 doses of implants, and 2 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 a 4-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=.16) and +2.4 and 3.1 letters (p=.073), respectively. However, nearly all phakic patients receiving implants developed cataracts and required cataract surgery. Further, most also developed glaucoma, with 75% of patients 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 an 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 an RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Results of this trial at 8 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 patients with a gain of ≥15 letters in best-corrected visual acuity from baseline was >40% with implants and 10% with sham). Further, at week 26, patients treated with implants reported meaningful increases in vision-related functioning. The major limitation of this trial was its lack of long-term follow-up. The use of implants resulted in higher incidences of cataracts and elevated intraocular pressure. The evidence is sufficient to determine that the technology results in an 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), the evidence includes 2 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) at both 6 and 12 months. However, serious limitations of these findings include inconsistency in the magnitude of the benefit at 12 months (odds ratio [OR], 67.09; 95% confidence interval [CI], 8.81 to 511.06 in published RCT and OR, 3.04; 95% CI, 1.52 to 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.

Macular Edema
For individuals with macular edema after retinal vein occlusion who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes 2 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 patients with a gain of 15 or more letters in best-corrected visual acuity from baseline was more than 10% in favor of implants versus sham in both studies at 30, 60, and 90 days, but not at 180 days postimplant. The 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 an improvement in the net health outcome.

For individuals with macular edema after retinal vein occlusion who receive an intravitreal fluocinolone acetonide implant (0.59 mg), no relevant 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.

Diabetic Macular Edema
For individuals with refractory (persistent or recurrent) diabetic macular edema who receive an intravitreal fluocinolone acetonide implant (0.59 mg), the evidence includes an 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 patients with implants reported clinically significant improvement in vision at 6 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 patients with phakic eyes who received implants required cataract surgery, and 60% developed elevated intraocular pressure. Due to the substantial increase in adverse events and availability of agents with better tolerability profiles (eg, antivascular endothelial growth factor), implant use in diabetic macular edema is questionable. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with diabetic macular edema who receive an intravitreal fluocinolone acetonide implant (0.19 mg), the evidence includes 2 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 vision at 2 and 3 years postimplant. The percentage of patients who gained 15 letters or more was 28.7% in the implant group versus 18.9% in the sham group at 3 years. Subgroup analysis showed greater improvements in visual acuity in patients who were pseudophakic compared with those who were phakic (difference in mean change in the number of letters at 2 years from baseline was 5.6 letters in pseudophakic patients vs. 1 letter in phakic patients). A major limitation of these implants is that nearly 80% of all phakic patients will develop cataracts and will require cataract surgery. Further, intraocular pressure was elevated in 34% of patients who received this implant compared with 10% of controls. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with diabetic macular edema who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes 3 RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Compared with sham control, 2 identically designed RCTs showed clinically meaningful improvements in vision with dexamethasone implants that peaked at 3 months and were maintained at 39 months (with retreatment). The difference in the proportion of patients with a gain of 15 or more letters in best-corrected visual acuity from baseline was 9.3% and 13.0% in the 2 trials, respectively, favoring implant versus sham at 39 months postimplant. Subgroup analysis of these trials showed greater improvements in visual acuity in patients 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 an improvement in the net health outcome.

For individuals with diabetic macular edema who receive an intravitreal dexamethasone implant (0.7 mg) plus antivascular endothelial growth factor therapy, the evidence includes 2 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, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with diabetic macular edema who receive an intravitreal dexamethasone implant (0.7 mg) plus laser photocoagulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 1-year follow-up demonstrated that combination implants plus laser photocoagulation compared with laser photocoagulation alone resulted in better visual acuity (as measured by a gain of ≥10 letters) at 9 months but not at 12 months. However, the generally accepted standard outcome measure for change is 15 or more letters, and this standard was not used in this trial. The use of dexamethasone implants resulted in higher incidences of cataracts and elevated intraocular pressure. Further, a differential loss to follow-up, lack of power calculations for sample size estimation, and lack of intention-to-treat analysis preclude the interpretation of results. A larger RCT with adequate power is needed to confirm these findings. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Age-Related Macular Degeneration

For individuals with age-related macular degeneration who receive an intravitreal dexamethasone implant (0.7 mg) plus antivascular endothelial growth factor inhibitor, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Results of this trial did not demonstrate clinically meaningful reductions in the ranibizumab injection-free interval between combined treatments (34 days) and antivascular endothelial growth factor alone (29 days; p=.016). Further, intraocular pressure was elevated in a greater proportion of patients receiving implants without any additional clinical benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Other Conditions

For individuals with birdshot retinochoroidopathy refractory or intolerant to standard therapy who receive an intravitreal fluocinolone acetonide implant (0.59 mg) or intravitreal dexamethasone implant (0.7 mg), the evidence includes multiple observational studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Multiple observational studies have noted improvements in anatomic and visual acuity outcomes. Long-term follow-up for efficacy and safety is limited. RCTs are needed to permit conclusions on the efficacy of corticosteroid implants in patients with refractory or intolerant birdshot retinochoroidopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cystoid macular edema who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes 1 observation controlled RCT (N=14), 3 comparative observational studies, and numerous case series. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The RCT found improved mean visual acuity and eye anatomy outcomes with intravitreal dexamethasone compared to the control eyes, but these differences were not sustained at 6 months. The comparative observational studies included 269 patients (range, 60 to 135) and also lacked responder analysis of the proportion of patients with a 15-or-more letter improvement. One case series evaluated the proportion of patients with a 3-line improvement in best-corrected visual acuity; although 88% of patients achieved this outcome at 2 months, the proportion with improvement was not sustained at 6 months (27.8%). Additional blinded, multicenter RCTs are needed that compare intravitreal dexamethasone to another established treatment. The trials should be adequately powered for measuring the proportion of patients in whom vision had improved by 15 letters or more. The

evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with idiopathic macular telangiectasia type 1 who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes multiple case reports. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Case reports have noted mixed results for visual acuity and inflammation-related outcomes. Long-term follow-up for efficacy and safety is limited. Better quality studies with long-term follow-up are needed to permit conclusions on the efficacy of corticosteroid implants in patients with idiopathic macular telangiectasia type 1. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with postoperative chronic macular edema (pseudophakic cystoid macular edema, Irvine-Gass syndrome) who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes 1 RCT (N=29) that compared dexamethasone intravitreal implant 0.7 mg to triamcinolone intravitreal injection 4 mg, 2 comparative observational studies, and numerous case series. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The RCT found no statistically significant difference between treatments in mean visual acuity improvement at 3 or 6 months. The proportion of patients in whom vision had improved by 15 letters or more was not reported. The comparative observational studies included only small numbers of patients and also lack responder analysis of the proportion of patients with a 15-or-more letter improvement. In the largest case series (N=100), 2 of every 5 patients experienced clinically meaningful improvements in visual acuity after 1 year of follow-up. Additional RCTs are needed that have clearly defined and representative populations (ie, for chronic and refractory patients, documentation of intensity and duration of the first-line therapy regimens) and are adequately powered for measuring the proportion of patients in whom vision had improved by 15 letters or more. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with circumscribed choroidal hemangiomas who receive an intravitreal dexamethasone implant (0.7 mg) plus photodynamic therapy, the evidence includes a case report. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Results of the case report do not permit conclusions about the efficacy or safety of adding dexamethasone implants for circumscribed choroidal hemangiomas to photodynamic therapy. RCTs are needed to permit conclusions on the efficacy of corticosteroid implants in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with proliferative vitreoretinopathy who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes a case series and a case report. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. These studies have reported multiple interventions, including dexamethasone implants in conjunction with surgery and laser for preventing proliferative retinopathy after retinal detachment surgery. RCTs are needed to permit conclusions on the efficacy of corticosteroid implants in patients with proliferative retinopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with radiation retinopathy who receive an intravitreal dexamethasone implant (0.7 mg), the evidence includes multiple observational studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Multiple observational studies have noted improvements in anatomic and visual acuity outcomes. Long-term follow-up for efficacy and safety is limited. RCTs are needed to permit conclusions on the efficacy of corticosteroid implants in patients with radiation retinopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with ocular inflammation and pain following ophthalmic surgery who receive punctum dexamethasone implant (0.4 mg), the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. All 3 trials noted significant improvements with the punctum dexamethasone insert (0.4 mg) across both coprimary efficacy endpoints of an absence of pain at 8 days and absence of anterior chamber cells at day 14. Adverse events were

generally similar between punctum dexamethasone insert (0.4 mg) and sham. Based on the consistent benefits and lack of important increases in adverse event risk, evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with noninfectious intermediate uveitis or posterior uveitis and cataract undergoing cataract surgery who receive prophylaxis with intravitreal dexamethasone implant (0.7 mg), the best evidence includes 1 single-center, open-label RCT of 43 patients in India. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Compared with oral corticosteroids, intravitreal dexamethasone 0.7 mg had similar benefits and avoided the need for early steroid taper due to adverse effects on blood glucose, but potentially increased risk of developing intraocular pressure. Due to important study limitations including its small sample size, unclear allocation concealment methods, and lack of blinding, evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with ocular itching associated with allergic conjunctivitis who receive punctum dexamethasone implant (0.4 mg), the evidence includes 3 RCTs, only 1 of which has been published. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Compared with the sham insert, punctum dexamethasone implant (0.4) demonstrated a significant decrease in patient-reported ocular itching after 1 week post-implant, and throughout most time points up to 30 days. Adverse events were similar in both groups and were all considered mild to moderate. However, limitations of this trial prevent evaluation of therapeutic use. It was not described if included participants had previously failed first-line therapies or if they were treatment-naive, making the intended use population unclear. If intended for use in treatment-naive patients, comparison to first-line topical agents is necessary for therapeutic evaluation. Additionally, the modified symptom scoring model used by investigators is typically only used in controlled, research settings, and not typically used for evaluation of therapeutic outcomes in real-world environments. The remaining approval trials (NCT02988882, NCT04050865) also found improved ocular itching with the punctum dexamethasone insert compared with vehicle control on day 8. However, the differences were generally smaller than those seen in the published trial and failed to reach significance in study NCT02988882. Due to the limitations of the published literature, and the lack of predefined clinically meaningful difference in symptom scores, the clinical significance of the primary outcome is unclear. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
11/2024	Off-cycle review. Policy revised. Policy statement added for new investigational indication for Dextenza for ocular itching associated with allergic conjunctivitis. Effective 11/2024.
5/2024	Annual policy review. Description, summary and references updated. Policy statements unchanged.
5/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
5/2022	Annual policy review. Editorial refinement to policy statement. Policy intent unchanged.
1/2022	New medically necessary indications added for fluocinolone acetonide 0.18 mg (Yutiq) for noninfectious posterior uveitis. Clarified coding information. 1/2022.
4/2021	Annual policy review. References updated. Policy statements unchanged.
8/2020	Annual policy review. Added new policy statements for all 3 new indications – medically necessary for Dextenza for individuals with ocular inflammation and pain following ophthalmic surgery; investigational for Yutiq for treatment of chronic noninfectious posterior uveitis affecting the posterior segment of the eye, and investigational for prophylactic Ozurdex for individuals with noninfectious intermediate uveitis or posterior uveitis and cataract undergoing cataract surgery. Policy title changed. Clarified coding information. Effective 8/1/2020.

1/2020	Clarified coding information.
10/2019	Clarified coding information.
4/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
4/2018	Annual policy review. New references added.
3/2018	Clarified coding information.
10/2017	Clarified coding information.
8/2017	Annual policy review. New investigational indications described. Policy statements revised to include the dose of dexamethasone intravitreal implant and fluocinolone acetonide intravitreal implant. Clarified coding information. Effective 8/1/2017.
7/2016	Annual policy review. Minor corrections made to language for consistency throughout.
4/2016	Annual policy review. New references added.
1/2016	Annual policy review. New references added.
3/2015	Annual policy review. New medically necessary indications described. Clarified coding information. Effective 3/1/2015.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
5/2014	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
2/2013	Annual policy review. Changes to policy statement. Effective 2/4/2013.
11/2011 -4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/1/2011	Annual policy review. Changes to policy statement. Effective 12/1/2011.
3/1/2011	New Medical Policy 272 effective 3/1/2011describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Haller JA, Bandello F, Belfort R, et al. Randomized, sham-controlled trial of dexamethasone intravitreal implant in patients with macular edema due to retinal vein occlusion. Ophthalmology. Jun 2010; 117(6): 1134-1146.e3. PMID 20417567
2. Haller JA, Bandello F, Belfort R, et al. Dexamethasone intravitreal implant in patients with macular edema related to branch or central retinal vein occlusion twelve-month study results. Ophthalmology. Dec 2011; 118(12): 2453-60. PMID 21764136
3. Bausch & Lomb Incorporated. Retisert (fluocinolone acetonide intravitreal implant) 0.59 mg: Prescribing Label. 2023; https://www.bausch.com/Portals/69/-/m/BL/United%20States/USFiles/Package%20Inserts/Pharma/retisert-prescribing-information.pdf?ver=2018-04-23-125740-133. Accessed February 6, 2024.
4. Jaffe GJ, Martin D, Callanan D, et al. Fluocinolone acetonide implant (Retisert) for noninfectious posterior uveitis: thirty-four-week results of a multicenter randomized clinical study. Ophthalmology. Jun 2006; 113(6): 1020-7. PMID 16690128
5. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Application Number: 22-315. Summary Review. 2009; http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022315s000_SumR.pdf. Accessed February 6, 2024.

6. Pavesio C, Zierhut M, Bairi K, et al. Evaluation of an intravitreal fluocinolone acetonide implant versus standard systemic therapy in noninfectious posterior uveitis. Ophthalmology. Mar 2010; 117(3): 567-75, 575.e1. PMID 20079922
7. Kempen JH, Altaweel MM, Holbrook JT, et al. Randomized comparison of systemic anti-inflammatory therapy versus fluocinolone acetonide implant for intermediate, posterior, and panuveitis: the multicenter uveitis steroid treatment trial. Ophthalmology. Oct 2011; 118(10): 1916-26. PMID 21840602
8. Kempen JH, Altaweel MM, Drye LT, et al. Benefits of Systemic Anti-inflammatory Therapy versus Fluocinolone Acetonide Intraocular Implant for Intermediate Uveitis, Posterior Uveitis, and Panuveitis: Fifty-four-Month Results of the Multicenter Uveitis Steroid Treatment (MUST) Trial and Follow-up Study. Ophthalmology. Oct 2015; 122(10): 1967-75. PMID 26298715
9. Jaffe GJ, Branchaud B, Hahn P, et al. Quality of Life and Risks Associated with Systemic Anti-inflammatory Therapy versus Fluocinolone Acetonide Intraocular Implant for Intermediate Uveitis, Posterior Uveitis, or Panuveitis: Fifty-four-Month Results of the Multicenter Uveitis Steroid Treatment Trial and Follow-up Study. Ophthalmology. Oct 2015; 122(10): 1976-86. PMID 26298718
10. Brady CJ, Villanti AC, Law HA, et al. Corticosteroid implants for chronic non-infectious uveitis. Cochrane Database Syst Rev. Feb 12 2016; 2(2): CD010469. PMID 26866343
11. Reddy A, Liu SH, Brady CJ, et al. Corticosteroid implants for chronic non-infectious uveitis. Cochrane Database Syst Rev. Jan 16 2023; 1(1): CD010469. PMID 36645716
12. Holbrook JT, Sugar EA, Burke AE, et al. Dissociations of the Fluocinolone Acetonide Implant: The Multicenter Uveitis Steroid Treatment (MUST) Trial and Follow-up Study. Am J Ophthalmol. Apr 2016; 164: 29-36. PMID 26748056
13. Lowder C, Belfort R, Lightman S, et al. Dexamethasone intravitreal implant for noninfectious intermediate or posterior uveitis. Arch Ophthalmol. May 2011; 129(5): 545-53. PMID 21220619
14. Lightman S, Belfort R, Naik RK, et al. Vision-related functioning outcomes of dexamethasone intravitreal implant in noninfectious intermediate or posterior uveitis. Invest Ophthalmol Vis Sci. Jul 18 2013; 54(7): 4864-70. PMID 23761087
15. Gillespie BW, Musch DC, Niziol LM, et al. Estimating minimally important differences for two vision-specific quality of life measures. Invest Ophthalmol Vis Sci. Jun 06 2014; 55(7): 4206-12. PMID 24906863
16. Allergan Inc. Ozurdex (dexamethasone intravitreal implant): Prescribing Label 2022; https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/20180515-OZURDEX-USPI-v1-0USPI3348.pdf. Accessed February 6, 2024.
17. U.S. Food and Drug Administration. Center for Drug Evaluation and Research, Application number 210331, Medical Review. 2018; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210331Orig1s000MedR.pdf. Accessed February 4, 2024.
18. Jaffe GJ, Foster CS, Pavesio CE, et al. Effect of an Injectable Fluocinolone Acetonide Insert on Recurrence Rates in Chronic Noninfectious Uveitis Affecting the Posterior Segment: Twelve-Month Results. Ophthalmology. Apr 2019; 126(4): 601-610. PMID 30367884
19. Jaffe GJ, Pavesio CE. Effect of a Fluocinolone Acetonide Insert on Recurrence Rates in Noninfectious Intermediate, Posterior, or Panuveitis: Three-Year Results. Ophthalmology. Oct 2020; 127(10): 1395-1404. PMID 32624244
20. Yeh S, Kim SJ, Ho AC, et al. Therapies for macular edema associated with central retinal vein occlusion: a report by the American Academy of Ophthalmology. Ophthalmology. Apr 2015; 122(4): 769-78. PMID 25576994
21. Pichi F, Specchia C, Vitale L, et al. Combination therapy with dexamethasone intravitreal implant and macular grid laser in patients with branch retinal vein occlusion. Am J Ophthalmol. Mar 2014; 157(3): 607-15.e1. PMID 24528934
22. Ehlers JP, Kim SJ, Yeh S, et al. Therapies for Macular Edema Associated with Branch Retinal Vein Occlusion: A Report by the American Academy of Ophthalmology. Ophthalmology. Sep 2017; 124(9): 1412-1423. PMID 28551163
23. Maturi RK, Chen V, Raghinaru D, et al. A 6-month, subject-masked, randomized controlled study to assess efficacy of dexamethasone as an adjunct to bevacizumab compared with bevacizumab alone in the treatment of patients with macular edema due to central or branch retinal vein occlusion. Clin Ophthalmol. 2014; 8: 1057-64. PMID 24940042

24. Gado AS, Macky TA. Dexamethasone intravitreous implant versus bevacizumab for central retinal vein occlusion-related macular oedema: a prospective randomized comparison. Clin Exp Ophthalmol. 2014; 42(7): 650-5. PMID 24612095
25. Kuppermann BD, Blumenkranz MS, Haller JA, et al. Randomized controlled study of an intravitreous dexamethasone drug delivery system in patients with persistent macular edema. Arch Ophthalmol. Mar 2007; 125(3): 309-17. PMID 17353400
26. Kumar P, Sharma YR, Chandra P, et al. Comparison of the Safety and Efficacy of Intravitreal Ranibizumab with or without Laser Photocoagulation Versus Dexamethasone Intravitreal Implant with or without Laser Photocoagulation for Macular Edema Secondary to Branch Retinal Vein Occlusion. Folia Med (Plovdiv). Jun 01 2019; 61(2): 240-248. PMID 31301668
27. Ji K, Zhang Q, Tian M, et al. Comparison of dexamethasone intravitreal implant with intravitreal anti-VEGF injections for the treatment of macular edema secondary to branch retinal vein occlusion: A meta-analysis. Medicine (Baltimore). May 2019; 98(22): e15798. PMID 31145307
28. Thorne JE, Sugar EA, Holbrook JT, et al. Periocular Triamcinolone vs. Intravitreal Triamcinolone vs. Intravitreal Dexamethasone Implant for the Treatment of Uveitic Macular Edema: The PeriOcular vs. INTravitreal corticosteroids for uveitic macular edema (POINT) Trial. Ophthalmology. Feb 2019; 126(2): 283-295. PMID 30269924
29. Fraser-Bell S, Kang HK, Mitchell P, et al. Dexamethasone intravitreal implant in treatment-naïve diabetic macular oedema: findings from the prospective, multicentre, AUSSIEDEX study. Br J Ophthalmol. Jan 2023; 107(1): 72-78. PMID 34433549
30. Zhang M, Liu Y, Song M, et al. Intravitreal Dexamethasone Implant Has Better Retinal Perfusion than Anti-Vascular Endothelial Growth Factor Treatment for Macular Edema Secondary to Retinal Vein Occlusion: A Five-Year Real-World Study. Ophthalmic Res. 2023; 66(1): 247-258. PMID 36215955
31. Rittiphairoj T, Mir TA, Li T, et al. Intravitreal steroids for macular edema in diabetes. Cochrane Database Syst Rev. Nov 17 2020; 11(11): CD005656. PMID 33206392
32. Grover D, Li TJ, Chong CC. Intravitreal steroids for macular edema in diabetes. Cochrane Database Syst Rev. Jan 23 2008; (1): CD005656. PMID 18254088
33. Pearson PA, Comstock TL, Ip M, et al. Fluocinolone acetonide intravitreal implant for diabetic macular edema: a 3-year multicenter, randomized, controlled clinical trial. Ophthalmology. Aug 2011; 118(8): 1580-7. PMID 21813090
34. Campochiaro PA, Brown DM, Pearson A, et al. Long-term benefit of sustained-delivery fluocinolone acetonide vitreous inserts for diabetic macular edema. Ophthalmology. Apr 2011; 118(4): 626-635.e2. PMID 21459216
35. Alimera Sciences Inc. Iluvien (fluocinolone acetonide intravitreal implant) 0.19 mg for Intravitreal Injection: Prescribing Label. 2016; https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed February 6, 2024.
36. Campochiaro PA, Brown DM, Pearson A, et al. Sustained delivery fluocinolone acetonide vitreous inserts provide benefit for at least 3 years in patients with diabetic macular edema. Ophthalmology. Oct 2012; 119(10): 2125-32. PMID 22727177
37. Cunha-Vaz J, Ashton P, Iezzi R, et al. Sustained delivery fluocinolone acetonide vitreous implants: long-term benefit in patients with chronic diabetic macular edema. Ophthalmology. Oct 2014; 121(10): 1892-903. PMID 24935282
38. Massin P, Erginay A, Dupas B, et al. Efficacy and safety of sustained-delivery fluocinolone acetonide intravitreal implant in patients with chronic diabetic macular edema insufficiently responsive to available therapies: a real-life study. Clin Ophthalmol. 2016; 10: 1257-64. PMID 27468222
39. Boyer DS, Yoon YH, Belfort R, et al. Three-year, randomized, sham-controlled trial of dexamethasone intravitreal implant in patients with diabetic macular edema. Ophthalmology. Oct 2014; 121(10): 1904-14. PMID 24907062
40. Gillies MC, Lim LL, Campain A, et al. A randomized clinical trial of intravitreal bevacizumab versus intravitreal dexamethasone for diabetic macular edema: the BEVORDEX study. Ophthalmology. Dec 2014; 121(12): 2473-81. PMID 25155371
41. U.S. National Library of Medicine. Dexamethasone Intravitreal Implant for the Treatment of Persistent Diabetic Macular Edema (DIME) NCT02471651. 2019. https://clinicaltrials.gov/ct2/show/results/NCT02471651?term=NCT02471651&draw=2&rank=1 Accessed February 6, 2024.

42. Callanan DG, Loewenstein A, Patel SS, et al. A multicenter, 12-month randomized study comparing dexamethasone intravitreal implant with ranibizumab in patients with diabetic macular edema. Graefes Arch Clin Exp Ophthalmol. Mar 2017; 255(3): 463-473. PMID 27632215
43. Sharma A, Bellala K, Dongre P, et al. Anti-VEGF versus dexamethasone implant (Ozurdex) for the management of Centre involved Diabetic Macular Edema (CiDME): a randomized study. Int Ophthalmol. Jan 2020; 40(1): 67-72. PMID 31377905
44. Cornish EE, Teo KY, Gillies MC, et al. Five-year outcomes of eyes initially enrolled in the 2-year BEVORDEX trial of bevacizumab or dexamethasone implants for diabetic macular oedema. Br J Ophthalmol. Jan 2023; 107(1): 79-83. PMID 34340975
45. Bolukbasi S, Cakir A, Erden B, et al. Comparison of the short-term effect of aflibercept and dexamethasone implant on serous retinal detachment in the treatment of naive diabetic macular edema. Cutan Ocul Toxicol. Dec 2019; 38(4): 401-405. PMID 31438736
46. Cakir A, Erden B, Bolukbasi S, et al. Comparison of the effect of ranibizumab and dexamethasone implant in diabetic macular edema with concurrent epiretinal membrane. J Fr Ophtalmol. Sep 2019; 42(7): 683-689. PMID 31088741
47. Coelho J, Malheiro L, Melo Beirão J, et al. Real-world retrospective comparison of 0.19 mg fluocinolone acetonide and 0.7 mg dexamethasone intravitreal implants for the treatment of diabetic macular edema in vitrectomized eyes. Clin Ophthalmol. 2019; 13: 1751-1759. PMID 31571814
48. Maturi RK, Glassman AR, Liu D, et al. Effect of Adding Dexamethasone to Continued Ranibizumab Treatment in Patients With Persistent Diabetic Macular Edema: A DRCR Network Phase 2 Randomized Clinical Trial. JAMA Ophthalmol. Jan 01 2018; 136(1): 29-38. PMID 29127949
49. Maturi RK, Bleau L, Saunders J, et al. A 12-MONTH, SINGLE-MASKED, RANDOMIZED CONTROLLED STUDY OF EYES WITH PERSISTENT DIABETIC MACULAR EDEMA AFTER MULTIPLE ANTI-VEGF INJECTIONS TO ASSESS THE EFFICACY OF THE DEXAMETHASONE-DELAYED DELIVERY SYSTEM AS AN ADJUNCT TO BEVACIZUMAB COMPARED WITH CONTINUED BEVACIZUMAB MONOTHERAPY. Retina. Aug 2015; 35(8): 1604-14. PMID 25829346
50. Callanan DG, Gupta S, Boyer DS, et al. Dexamethasone intravitreal implant in combination with laser photocoagulation for the treatment of diffuse diabetic macular edema. Ophthalmology. Sep 2013; 120(9): 1843-51. PMID 23706947
51. Kuppermann BD, Goldstein M, Maturi RK, et al. Dexamethasone Intravitreal Implant as Adjunctive Therapy to Ranibizumab in Neovascular Age-Related Macular Degeneration: A Multicenter Randomized Controlled Trial. Ophthalmologica. 2015; 234(1): 40-54. PMID 26088793
52. Bajwa A, Aziz K, Foster CS. Safety and efficacy of fluocinolone acetonide intravitreal implant (0.59 mg) in birdshot retinochoroidopathy. Retina. Nov 2014; 34(11): 2259-68. PMID 24999722
53. Burkholder BM, Wang J, Dunn JP, et al. Postoperative outcomes after fluocinolone acetonide implant surgery in patients with birdshot chorioretinitis and other types of posterior and panuveitis. Retina. Sep 2013; 33(8): 1684-93. PMID 23549097
54. Rush RB, Goldstein DA, Callanan DG, et al. Outcomes of birdshot chorioretinopathy treated with an intravitreal sustained-release fluocinolone acetonide-containing device. Am J Ophthalmol. Apr 2011; 151(4): 630-6. PMID 21277557
55. Srour M, Querques G, Leveziel N, et al. Intravitreal dexamethasone implant (Ozurdex) for macular edema secondary to retinitis pigmentosa. Graefes Arch Clin Exp Ophthalmol. Jun 2013; 251(6): 1501-6. PMID 23275039
56. Erdoğan G, Aydoğan T, Ünlü C, et al. Dexamethasone Implant for the Treatment of Type 1 Idiopathic Macular Telangiectasia. J Ocul Pharmacol Ther. May 2016; 32(4): 211-5. PMID 26985700
57. Donati S, Gandolfi C, Caprani SM, et al. Evaluation of the Effectiveness of Treatment with Dexamethasone Intravitreal Implant in Cystoid Macular Edema Secondary to Retinal Vein Occlusion. Biomed Res Int. 2018; 2018: 3095961. PMID 30175123
58. Laine I, Lindholm JM, Ylinen P, et al. Intravitreal bevacizumab injections versus dexamethasone implant for treatment-naïve retinal vein occlusion related macular edema. Clin Ophthalmol. 2017; 11: 2107-2112. PMID 29225460
59. Spaide RF. RETINAL VASCULAR CYSTOID MACULAR EDEMA: Review and New Theory. Retina. Oct 2016; 36(10): 1823-42. PMID 27328171
60. Ozkok A, Saleh OA, Sigford DK, et al. THE OMAR STUDY: Comparison of Ozurdex and Triamcinolone Acetonide for Refractory Cystoid Macular Edema in Retinal Vein Occlusion. Retina. Jul 2015; 35(7): 1393-400. PMID 25748280

61. Csaky KG, Richman EA, Ferris FL. Report from the NEI/FDA Ophthalmic Clinical Trial Design and Endpoints Symposium. Invest Ophthalmol Vis Sci. Feb 2008; 49(2): 479-89. PMID 18234989
62. Park UC, Park JH, Ma DJ, et al. A RANDOMIZED PAIRED-EYE TRIAL OF INTRAVITREAL DEXAMETHASONE IMPLANT FOR CYSTOID MACULAR EDEMA IN RETINITIS PIGMENTOSA. Retina. Jul 2020; 40(7): 1359-1366. PMID 31166248
63. Veritti D, Sarao V, De Nadai K, et al. Dexamethasone Implant Produces Better Outcomes than Oral Acetazolamide in Patients with Cystoid Macular Edema Secondary to Retinitis Pigmentosa. J Ocul Pharmacol Ther. Apr 2020; 36(3): 190-197. PMID 31886707
64. Novais EA, Maia M, Filho PA, et al. Twelve-Month Follow-Up of Dexamethasone Implants for Macular Edema from Various Diseases in Vitrectomized and Nonvitrectomized Eyes. J Ophthalmol. 2016; 2016: 7984576. PMID 27721989
65. Bansal P, Agarwal A, Gupta V, et al. Spectral domain optical coherence tomography changes following intravitreal dexamethasone implant, Ozurdex® in patients with uveitic cystoid macular edema. Indian J Ophthalmol. May 2015; 63(5): 416-22. PMID 26139803
66. Fortoul V, Denis P, Kodjikian L. Anatomical and functional recurrence after dexamethasone intravitreal implants: a 6-month prospective study. Eye (Lond). Jun 2015; 29(6): 769-75. PMID 25853447
67. Bezatis A, Spital G, Höhn F, et al. Functional and anatomical results after a single intravitreal Ozurdex injection in retinal vein occlusion: a 6-month follow-up -- the SOLO study. Acta Ophthalmol. Aug 2013; 91(5): e340-7. PMID 23638803
68. Lei S, Lam WC. Efficacy and safety of dexamethasone intravitreal implant for refractory macular edema in children. Can J Ophthalmol. Jun 2015; 50(3): 236-41. PMID 26040225
69. Loutfi M, Papathomas T, Kamal A. Macular oedema related to idiopathic macular telangiectasia type 1 treated with dexamethasone intravitreal implant (ozurdex). Case Rep Ophthalmol Med. 2014; 2014: 231913. PMID 25045562
70. Holló G, Aung T, Cantor LB, et al. Cystoid macular edema related to cataract surgery and topical prostaglandin analogs: Mechanism, diagnosis, and management. Surv Ophthalmol. 2020; 65(5): 496-512. PMID 32092363
71. Grzybowski A, Sikorski BL, Ascaso FJ, et al. Pseudophakic cystoid macular edema: update 2016. Clin Interv Aging. 2016; 11: 1221-1229. PMID 27672316
72. Mylonas G, Georgopoulos M, Malamos P, et al. Comparison of Dexamethasone Intravitreal Implant with Conventional Triamcinolone in Patients with Postoperative Cystoid Macular Edema. Curr Eye Res. Apr 2017; 42(4): 648-652. PMID 27612922
73. Dang Y, Mu Y, Li L, et al. Comparison of dexamethasone intravitreal implant and intravitreal triamcinolone acetonide for the treatment of pseudophakic cystoid macular edema in diabetic patients. Drug Des Devel Ther. 2014; 8: 1441-9. PMID 25258512
74. Guclu H, Pelitli Gurlu V. Comparison of topical nepafenac 0.1% with intravitreal dexamethasone implant for the treatment of Irvine-Gass syndrome. Int J Ophthalmol. 2019; 12(2): 258-267. PMID 30809482
75. Klamann A, Böttcher K, Ackermann P, et al. Intravitreal Dexamethasone Implant for the Treatment of Postoperative Macular Edema. Ophthalmologica. 2016; 236(4): 181-185. PMID 27915343
76. Sudhalkar A, Chhablani J, Vasavada A, et al. Intravitreal dexamethasone implant for recurrent cystoid macular edema due to Irvine-Gass syndrome: a prospective case series. Eye (Lond). Dec 2016; 30(12): 1549-1557. PMID 27858937
77. Keilani C, Halalchi A, Wakpi Djeugue D, et al. Evaluation of best corrected visual acuity and central macular thickness after intravitreal dexamethasone implant injections in patients with Irvine-Gass syndrome: A retrospective study of six cases. Therapie. Oct 2016; 71(5): 457-465. PMID 27203164
78. Mayer WJ, Kurz S, Wolf A, et al. Dexamethasone implant as an effective treatment option for macular edema due to Irvine-Gass syndrome. J Cataract Refract Surg. Sep 2015; 41(9): 1954-61. PMID 26603404
79. Landré C, Zourdani A, Gastaud P, et al. [Treatment of postoperative cystoid macular edema (Irvine-Gass syndrome) with dexamethasone 0.7 mg intravitreal implant]. J Fr Ophtalmol. Jan 2016; 39(1): 5-11. PMID 26520410
80. Degoumois A, Akesbi J, Laurens C, et al. [Efficacy of intravitreal dexamethasone implants in macular edema excluding venous occlusions: results for a cohort of 80 patients]. J Fr Ophtalmol. Feb 2015; 38(2): 126-33. PMID 25592383

81. Dutra Medeiros M, Navarro R, Garcia-Arumí J, et al. Dexamethasone intravitreal implant for treatment of patients with recalcitrant macular edema resulting from Irvine-Gass syndrome. Invest Ophthalmol Vis Sci. May 07 2013; 54(5): 3320-4. PMID 23599334
82. Freissinger S, Vounotrypidis E, Wolf A, et al. Evaluation of Functional Outcomes and OCT-Biomarkers after Intravitreal Dexamethasone Implant for Postoperative Cystoid Macular Edema in Vitrectomized Eyes. J Ophthalmol. 2020; 2020: 3946531. PMID 32411428
83. Bellocq D, Pierre-Kahn V, Matonti F, et al. Effectiveness and safety of dexamethasone implants for postsurgical macular oedema including Irvine-Gass syndrome: the EPISODIC-2 study. Br J Ophthalmol. Mar 2017; 101(3): 333-341. PMID 27190126
84. Bazin L, Gambrelle J. [Combined treatment with photodynamic therapy and intravitreal dexamethasone implant (Ozurdex(®)) for circumscribed choroidal hemangioma]. J Fr Ophtalmol. Dec 2012; 35(10): 798-802. PMID 23040445
85. Sherif M, Wolfensberger TJ. Intraocular Dexamethasone Implant as Adjunct to Silicone Oil Tamponade for Proliferative Vitreoretinopathy. Klin Monbl Augenheilkd. Apr 2017; 234(4): 501-504. PMID 28147403
86. Reibaldi M, Russo A, Longo A, et al. Rhegmatogenous Retinal Detachment with a High Risk of Proliferative Vitreoretinopathy Treated with Episcleral Surgery and an Intravitreal Dexamethasone 0.7-mg Implant. Case Rep Ophthalmol. Jan 2013; 4(1): 79-83. PMID 23687501
87. Caminal JM, Flores-Moreno I, Arias L, et al. INTRAVITREAL DEXAMETHASONE IMPLANT FOR RADIATION MACULOPATHY SECONDARY TO PLAQUE BRACHYTHERAPY IN CHOROIDAL MELANOMA. Retina. Sep 2015; 35(9): 1890-7. PMID 26035401
88. Bui KM, Chow CC, Mieler WF. Treatment of recalcitrant radiation maculopathy using intravitreal dexamethasone (Ozurdex) implant. Retin Cases Brief Rep. 2014; 8(3): 167-70. PMID 25372430
89. Baillif S, Maschi C, Gastaud P, et al. Intravitreal dexamethasone 0.7-mg implant for radiation macular edema after proton beam therapy for choroidal melanoma. Retina. Oct 2013; 33(9): 1784-90. PMID 23652581
90. Tyson SL, Bafna S, Gira JP, et al. Multicenter randomized phase 3 study of a sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery. J Cataract Refract Surg. Feb 2019; 45(2): 204-212. PMID 30367938
91. Walters T, Bafna S, Vold S, Wortz G, Harton P, et al. (2016) Efficacy and Safety of Sustained Release Dexamethasone for the Treatment of Ocular Pain and Inflammation after Cataract Surgery: Results from Two Phase 3 Studies. J Clin Exp Ophthalmol 7:1000572. doi: 10.4172/2155-9570.1000572
92. Sudhalkar A, Vasavada A, Bhojwani D, et al. Intravitreal dexamethasone implant as an alternative to systemic steroids as prophylaxis for uveitic cataract surgery: a randomized trial. Eye (Lond). Mar 2020; 34(3): 491-498. PMID 31320735
93. Ocular Therapeutix, Inc. Dextenza (dexamethasone ophthalmic insert) 0.4 mg: Prescribing Label. 2021; www.dextenza.com/wp-content/uploads/DEXTENZA-Full-Prescribing-Information.pdf. Accessed May 7, 2024.
94. McLaurin EB, Evans D, Repke CS, et al. Phase 3 Randomized Study of Efficacy and Safety of a Dexamethasone Intracanalicular Insert in Patients With Allergic Conjunctivitis. Am J Ophthalmol. Sep 2021; 229: 288-300. PMID 33773984
95. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern®. Ophthalmology. Feb 2020; 127(2): P288-P320. PMID 31757503
96. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern®. Ophthalmology. Jan 2020; 127(1): P66-P145. PMID 31757498
97. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern®. Ophthalmology. Jan 2020; 127(1): P1-P65. PMID 31757502
98. Cheung AY, Choi DS, Ahmad S, et al. Conjunctivitis Preferred Practice Pattern. Ophthalmology. Apr 2024; 131(4): P134-P204. PMID 38349304
99. National Institute for Health and Care Excellence (NICE). Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy Technology appraisal guidance [TA613], 2019. https://www.nice.org.uk/guidance/ta613 Accessed February 2, 2024.
100. National Institute for Health and Care Excellence (NICE). Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uveitis Technology appraisal guidance [TA590] 2019; https://www.nice.org.uk/guidance/TA590/chapter/1-Recommendations Accessed February 1, 2024.

101. National Institute for Health and Care Excellence (NICE). Adalimumab and dexamethasone for treating non- infectious uveitis [TA460]. 2017; https://www.nice.org.uk/guidance/ta460. Accessed February 5, 2024.
102. National Institute for Health and Care Excellence (NICE). Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion [TA229]. 2011; https://www.nice.org.uk/guidance/ta229. Accessed February 6, 2024.
103. National Institute for Health and Care Excellence (NICE). Dexamethasone intravitreal implant for treating diabetic macular oedema [TA349]. 2022; https://www.nice.org.uk/guidance/TA824. Accessed February 4, 2024.
104. National Institute for Health and Care Excellence (NICE). Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy [TA301]. 2013; https://www.nice.org.uk/guidance/ta301. Accessed February 3, 2024.

Endnotes

[1] Based on expert opinion