

EFFECTIVE DATE: 10 | 1 | 2015

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OVERVIEW

An intravitreal implant is a drug delivery system, injected or surgically implanted in the vitreous of the eye, for sustained release of drug to the posterior and intermediate segments of the eye. Intravitreal corticosteroid implants are being investigated for a variety of inflammatory eye conditions.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

A fluocinolone acetonide intravitreal implant approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary for the treatment of: chronic noninfectious intermediate, posterior, or panuveitis (Retisert®), diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (ILUVIEN®)

A dexamethasone intravitreal implant approved by FDA (i.e., Ozurdex™) may be considered medically necessary for the treatment of: Noninfectious ocular inflammation, or uveitis, affecting the intermediate or posterior segment of the eye, macular edema following branch or central retinal vein occlusion, or diabetic macular edema.

All other uses of a corticosteroid intravitreal implant are considered not medically necessary as not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable physician administered injectable drug benefits/coverage.

BACKGROUND

Intravitreal implants are being developed to deliver a continuous concentration of drug over a prolonged period of time. Intravitreal corticosteroid implants are being studied for a variety of eye conditions leading to macular edema, including uveitis, diabetic retinopathy, and retinal venous occlusions. The goal of therapy is to reduce the inflammatory process in the eye while minimizing the adverse effects 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 its own drawbacks. For example, topical corticosteroids require frequent (e.g., 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 effects such as hypertension and osteoporosis, while repeated (every 4-6 weeks) intraocular corticosteroid injections may result in pain, intraocular infection, globe perforation, fibrosis of the extraocular muscles, reactions to the delivery vehicle, increased IOP, and cataract development.

Corticosteroid implants may be either 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, surgical implantation of the device carries its own risks, and the implant could potentially 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:

- Retisert® (nonbiodegradable fluocinolone acetonide intravitreal implant; Bausch & Lomb) sterile implant consists of a tablet containing 0.59 mg fluocinolone acetonide, 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 a period of approximately 2.5 years.
- ILUVIEN® (nonbiodegradable injectable intravitreal implant with fluocinolone acetonide; Alimera Sciences Inc.) is a rod-shaped device made of polyimide and polyvinyl alcohol. It is small enough to be placed using an inserter with a 25-gauge needle and is expected to provide sustained delivery of fluocinolone acetonide for up to 3 years.
- Ozurdex® or Posurdex® (biodegradable dexamethasone intravitreal implant; Allergan, Irvine, CA) 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.

Uveitis

Uveitis encompasses a variety of conditions, of either infectious or noninfectious etiologies, that are characterized by inflammation of any part of the uveal tract of the eye (iris, ciliary body, choroid). Infectious etiologies include syphilis, toxoplasmosis, cytomegalovirus retinitis, and candidiasis. Noninfectious etiologies include sarcoidosis, Behçet syndrome, and “white dot” syndromes such as multifocal choroiditis or “birdshot” chorioretinopathy. Uveitis may also 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 (SUN) 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 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 and glaucoma and to structural damage to the eye, resulting in severe and permanent vision loss. Noninfectious uveitis typically responds well to corticosteroid treatment. Immunosuppressive therapy (e.g., 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.

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 provide nourishment to the retina are blocked, triggering the growth of new

and fragile blood vessels (proliferative retinopathy). Severe vision loss with proliferative retinopathy arises from leakage of blood into the vitreous. DME is characterized by swelling of the macula due to gradual leakage of fluids from blood vessels and breakdown of the blood-retinal barrier. Moderate vision loss can arise from the fluid accumulating in the center of the macula (macular edema) during the proliferative or nonproliferative stages of the disease. Although 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.

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. Intravitreal injection of triamcinolone acetonide is used as an off-label adjunctive therapy for DME, and intravitreal steroid implants are being evaluated. Angiostatic agents such as injectable vascular endothelial growth factor (VEGF) inhibitors, which block some stage in the pathway leading to new blood vessel formation (angiogenesis), have demonstrated efficacy in DME.

Retinal Vein Occlusion

Retinal vein occlusions are classified by whether the central retinal vein or one of its branches is obstructed. CRVO and BRVO differ with respect to pathophysiology, clinical course, and therapy. CRVOs are also categorized as ischemic or nonischemic. Ischemic CRVOs are referred to as severe, complete, or total vein obstruction and account for 20% to 25% of all CRVOs. Macular edema and permanent macular dysfunction occur in virtually all patients with ischemic CRVO, and in many patients with nonischemic CRVO. Intravitreal injections of triamcinolone are used to treat macular edema associated with CRVO, 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.

BRVO is a common retinal vascular disorder in adults between 60 and 70 years of age and occurs approximately 3 times more commonly than CRVO. Macular photocoagulation with grid laser improves vision in BRVO but is not recommended for CRVO. Although intravitreal injections of triamcinolone have also been used for BRVO, the serious adverse effects have stimulated the evaluation of new treatments, including intravitreal steroid implants or the intravitreal injection of antivascular endothelial growth factor (anti-VEGF).

The evidence on intravitreal corticosteroid implants includes a number of high-quality trials that have been submitted for U.S. Food and Drug Administration (FDA) approval. Overall, results show a modest improvement in visual outcomes in a relatively small number of patients, with a significantly higher rate of cataracts and increased intraocular pressure (IOP) when compared with controls. As a result, one of the FDA-approved indications limits treatment to those patients who have previously shown an improvement with corticosteroid treatment without an increase in IOP. Intravitreal implants might be considered a reasonable alternative when patients are intolerant or refractory to systemic therapy, or in patients for whom systemic steroid-related adverse effects are expected to be more frequent and/or severe than the ocular adverse effects.

Use of corticosteroid implants/inserts may be considered medically necessary for the FDA-approved indications. Given the modest improvement in vision and the potential for adverse events, informed decision making is a key part of this process. Patients should be informed about the potential for cataracts, increased IOP or hypotony, endophthalmitis, and risk of need for additional surgical procedures

CODING

Blue CHip for Medicare and Commercial Products

The following codes are covered when filed with an approved diagnosis noted below:

J7311 Fluocinolone acetonide, intravitreal implant

J7312 Injection, dexamethasone, intravitreal implant, 0.1 mg

Medically necessary ICD-10 diagnosis



intravitreal
corticosteroid implant

RELATED POLICIES

Suprachoroidal Delivery of Pharmacologic Agents

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