

# Ozurdex<sup>®</sup>

(dexamethasone intravitreal  
implant) 0.7 mg

## Billing and Coding Guidelines

(Rev: 02/2020)

### Indications and Usage

#### Diabetic Macular Edema

OZURDEX<sup>®</sup> (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of diabetic macular edema.

#### Retinal Vein Occlusion

OZURDEX<sup>®</sup> is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

#### Posterior Segment Uveitis

OZURDEX<sup>®</sup> is indicated for the treatment of noninfectious uveitis affecting the posterior segment of the eye.

### IMPORTANT SAFETY INFORMATION

#### Contraindications

**Ocular or Periocular Infections:** OZURDEX<sup>®</sup> (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

**Please see additional Important Safety Information on the following pages.**

## The Following Codes May Apply to OZURDEX<sup>®</sup>

Product Codes		
Code Type	Code	Descriptor
HCPCS	J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg
NDC	00023-3348-07	OZURDEX <sup>®</sup> (dexamethasone intravitreal implant) 0.7 mg
<i>CPT</i> <sup>®a</sup> <i>CPT</i> <sup>®</sup> codes may vary. Please check with your payer.	67028	Intravitreal injection of a pharmacologic agent (separate procedure)
Modifier	-LT, -RT	Indicates left side (-LT), or right side (-RT)
Modifier	50	Indicates bilateral services (in both eyes)

For appropriate reimbursement, follow this important coding guidance:

- Each OZURDEX<sup>®</sup> implant is 0.7 mg and should be billed as 7 units using J7312

<sup>a</sup>*CPT*<sup>®</sup> codes and descriptors are copyrighted by the AMA. The procedure codes are for illustrative purposes only, as the practitioner must determine the proper coding for the treatment provided.

### **IMPORTANT SAFETY INFORMATION (continued)**

#### **Contraindications (continued)**

**Glaucoma:** OZURDEX<sup>®</sup> (dexamethasone intravitreal implant) is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.

**Torn or Ruptured Posterior Lens Capsule:** OZURDEX<sup>®</sup> is contraindicated in patients whose posterior lens capsule is torn or ruptured because of the risk of migration into the anterior chamber. Laser posterior capsulotomy in pseudophakic patients is not a contraindication for OZURDEX<sup>®</sup> use.

**Hypersensitivity:** OZURDEX<sup>®</sup> is contraindicated in patients with known hypersensitivity to any components of this product.

**Please see additional Important Safety Information on the following pages.**

# ICD-10-CM Codes for Diabetic Macular Edema

**Note: Coverage and coding requirements vary by payer, so be sure to conduct a benefit verification and check payer policy prior to treatment.**

## OZURDEX® ICD-10-CM Codes

Code	Descriptor
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
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
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
E11.3311	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
E11.3411	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
E11.3511	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

Remember, ICD-10-CM codes submitted to the payer must accurately describe the diagnosis for which the patient receives OZURDEX® treatment, represent codes at the highest level of specificity, and reflect the contents of any clinical notes and/or chart documentation. Such codes should also be included in a letter of medical necessity or request for prior authorization, where required (or accepted) by the patient's payer.

This coding information contained herein is gathered from various resources and is subject to change. This document is intended for reference only. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment for OZURDEX®. Third-party payment for medical products and services is affected by numerous factors. The decision about which code to report must be made by the provider/physician considering the clinical facts, circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity. Please refer to your Medicare policy/other payer policies for specific guidance.



# ICD-10-CM Codes for Retinal Vein Occlusion

**Note: Coverage and coding requirements vary by payer, so be sure to conduct a benefit verification and check payer policy prior to treatment.**

## OZURDEX® ICD-10-CM Codes

Code	Descriptor
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

### IMPORTANT SAFETY INFORMATION (continued)

#### Warnings and Precautions

**Intravitreal Injection-related Effects:** Intravitreal injections, including those with OZURDEX® (dexamethasone intravitreal implant), have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored regularly following the injection.

**Steroid-related Effects:** Use of corticosteroids including OZURDEX® may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

**Please see additional Important Safety Information on the following pages.**

# ICD-10-CM Codes for Noninfectious Posterior Segment Uveitis

**Note: Coverage and coding requirements vary by payer, so be sure to conduct a benefit verification and check payer policy prior to treatment.**

## OZURDEX® ICD-10-CM Codes

Code	Descriptor
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
H30.031	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

Remember, ICD-10-CM codes submitted to the payer must accurately describe the diagnosis for which the patient receives OZURDEX® treatment, represent codes at the highest level of specificity, and reflect the contents of any clinical notes and/or chart documentation. Such codes should also be included in a letter of medical necessity or request for prior authorization, where required (or accepted) by the patient's payer.

This coding information contained herein is gathered from various resources and is subject to change. This document is intended for reference only. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment for OZURDEX®. Third-party payment for medical products and services is affected by numerous factors. The decision about which code to report must be made by the provider/physician considering the clinical facts, circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity. Please refer to your Medicare policy/other payer policies for specific guidance.

# ICD-10-CM Codes for Noninfectious Posterior Segment Uveitis (continued)

**Note: Coverage and coding requirements vary by payer, so be sure to conduct a benefit verification and check payer policy prior to treatment.**

## OZURDEX® ICD-10-CM Codes

Code	Descriptor
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
H30.121	Disseminated chorioretinal inflammation, peripheral, right eye
H30.122	Disseminated chorioretinal inflammation, peripheral, left eye
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral
H30.131	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	Disseminated chorioretinal inflammation, generalized, 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

### IMPORTANT SAFETY INFORMATION (continued)

#### Adverse Reactions

#### Diabetic Macular Edema

Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of OZURDEX® (dexamethasone intravitreal implant) for diabetic macular edema include: cataract (68%), conjunctival hemorrhage (23%), visual acuity reduced (9%), conjunctivitis (6%), vitreous floaters (5%), conjunctival edema (5%), dry eye (5%), vitreous detachment (4%), vitreous opacities (3%), retinal aneurysm (3%), foreign body sensation (2%), corneal erosion (2%), keratitis (2%), anterior chamber inflammation (2%), retinal tear (2%), eyelid ptosis (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: hypertension (13%) and bronchitis (5%).

**Please see additional Important Safety Information on the back page.**

# ICD-10-CM Codes for Noninfectious Posterior Segment Uveitis (continued)

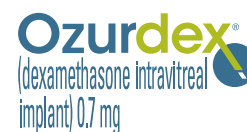
**Note: Coverage and coding requirements vary by payer, so be sure to conduct a benefit verification and check payer policy prior to treatment.**

## OZURDEX® ICD-10-CM Codes

Code	Descriptor
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
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral

Remember, ICD-10-CM codes submitted to the payer must accurately describe the diagnosis for which the patient receives OZURDEX® treatment, represent codes at the highest level of specificity, and reflect the contents of any clinical notes and/or chart documentation. Such codes should also be included in a letter of medical necessity or request for prior authorization, where required (or accepted) by the patient's payer.

This coding information contained herein is gathered from various resources and is subject to change. This document is intended for reference only. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment for OZURDEX®. Third-party payment for medical products and services is affected by numerous factors. The decision about which code to report must be made by the provider/physician considering the clinical facts, circumstances, and applicable coding rules, including the requirement to code to the highest level of specificity. Please refer to your Medicare policy/other payer policies for specific guidance.



# Ozurdex<sup>®</sup>

(dexamethasone intravitreal implant) 0.7 mg

## IMPORTANT SAFETY INFORMATION (continued)

### Adverse Reactions (continued)

#### Diabetic Macular Edema (continued)

**Increased Intraocular Pressure:** IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 28% of OZURDEX<sup>®</sup> (dexamethasone intravitreal implant) patients versus 4% of sham patients. 42% of the patients who received OZURDEX<sup>®</sup> were subsequently treated with IOP-lowering medications during the study versus 10% of sham patients.

The increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles (at the end of the 6-month period).

**Cataracts and Cataract Surgery:** The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX<sup>®</sup> group (68%) compared with Sham (21%). The median time of cataract being reported as an adverse event was approximately 15 months in the OZURDEX<sup>®</sup> group and 12 months in the Sham group. Among these patients, 61% of OZURDEX<sup>®</sup> subjects versus 8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX<sup>®</sup> group and 20 for Sham) of the studies.

#### Retinal Vein Occlusion and Posterior Segment Uveitis

Adverse reactions reported by greater than 2% of patients in the first 6 months following injection of OZURDEX<sup>®</sup> for retinal vein occlusion and posterior segment uveitis include: intraocular pressure increased (25%), conjunctival hemorrhage (22%), eye pain (8%), conjunctival hyperemia (7%), ocular hypertension (5%), cataract (5%), vitreous detachment (2%), and headache (4%).

Increased IOP with OZURDEX<sup>®</sup> peaked at approximately week 8. During the initial treatment period, 1% (3/421) of the patients who received OZURDEX<sup>®</sup> required surgical procedures for management of elevated IOP.

#### Dosage and Administration

FOR OPHTHALMIC INTRAVITREAL INJECTION. The intravitreal injection procedure should be carried out under controlled aseptic conditions. Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

**Please see accompanying full Prescribing Information.**

