Ozurdex® (dexamethasone implant) (Intravitreal)

I. Length of Authorization

Coverage will be provided for 1 implant per affected eye every 4 to 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Ozurdex 0.7 mg intravitreal implant: 2 implants every 4 months

B. Max Units (per dose and over time) [Medical Benefit]:
   - 14 billable units every 4 months

(Quantity Limits/Max units are based on administration to BOTH eyes)

III. Initial Approval Criteria

- Patient is at least 18 years of age; AND
- Patient is free of ocular or periorbital infections; AND
- Patient does not have glaucoma with a cup to disk ratio of greater than 0.8; AND
- Patient does not have a torn or ruptured posterior lens capsule; AND
- Must not be used in combination with other sustained-release intravitreal corticosteroids; AND

Coverage is provided in the following conditions:

Diabetic Macular Edema (DME) †

- Patient has had an inadequate response or has a contraindication to treatment with bevacizumab intravitreal injection (the contraindication must be specified) prior to Ozurdex consideration.

Macular Edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) †
• Patient has had an inadequate response or has a contraindication to treatment with bevacizumab intravitreal injection (the contraindication must be specified) prior to Ozurdex consideration.

**Non-infectious uveitis affecting the posterior segment of the eye †**

• Patient has had an inadequate response (i.e., unresolved uveitis) or has a contraindication to treatment with triamcinolone acetonide intravitreal injection (the contraindication must be specified): **OR**

• Patient is receiving triamcinolone acetonide intravitreal injection but requires injections more often than every 12 weeks

† FDA Approved Indication(s)

### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

• Patient continues to meet the criteria identified in section III: **AND**

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cataract, increased intraocular pressure, endophthalmitis, and conjunctival hemorrhage, etc: **AND**

• Disease response as indicated by:

**Retinal Vein Occlusion Macular Edema/Diabetic Macular Edema**

• Stabilization of visual acuity or improvement in best-corrected visual acuity (BCVA) score when compared to baseline

**Posterior Segment Uveitis**

• Stabilization of visual acuity or improvement in BCVA score when compared to baseline: **OR**

• Improvement in vitreous haze score (decrease in inflammation)

### V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tr>
<td>All indications</td>
<td>One ophthalmic intravitreal injection (containing 0.7 mg dexamethasone implant) into affected eye(s) once per 4 to 6 months</td>
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</tbody>
</table>

### VI. Billing Code/Availability Information

**Jcode:**

• J7312 - Injection, dexamethasone, intravitreal implant, 0.1 mg; 0.1 mg = 1 billable units

**NDC:**

• Ozurdex 0.7 mg intravitreal implant: 00023-3348-xx

### VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>Description</th>
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<tr>
<td>E08.311</td>
<td>Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema</td>
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<td>Retinal edema</td>
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</table>

**Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
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<td>H (4 &amp; 7)</td>
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<td>Novitas Solutions, Inc.</td>
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<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
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<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto Government Benefit Administrators, LLC</td>
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<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
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<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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