PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Iluvien (fluocinolone acetonide)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J7313</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office</td>
</tr>
<tr>
<td>STATUS</td>
<td>Prior Authorization Required</td>
</tr>
</tbody>
</table>

Iluvien is an intravitreal implant containing 0.19 mg (190 mcg) fluocinolone acetonide in a 36-month sustained-release drug delivery system. It is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. DME is a common complication of diabetic retinopathy.

Iluvien (fluocinolone acetonide) will be considered for coverage when the following criteria are met:

### Diabetic Macular Edema (DME)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a confirmed diagnosis of diabetic macular edema; AND
4. Member has been previously treated with a course of corticosteroids and did not have a clinically significant increase in intraocular pressure; AND
5. Member has tried and failed Ozurdex; AND
6. Member does not have active or suspected ocular or periocular infection; AND
7. Member does not have glaucoma with a cup to disc ratio greater than 0.8.
8. **Dosage allowed/Quantity limit**: One implant (0.19 mg) per eye  
Limit: 2 implants (1 per eye) per 36 months.

**If all the above requirements are met, the medication will be approved for 3 months.**

For **reauthorization**:
1. Chart notes must show improved or stabilized visual acuity following treatment; AND
2. At least 36 months have elapsed since the prior treatment (of the same eye).

**If all the above requirements are met, the medication will be approved for an additional 3 months.**

CareSource considers Iluvien (fluocinolone acetonide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/27/2021</td>
<td>New policy created for Iluvien.</td>
</tr>
</tbody>
</table>

Effective date: 04/01/2022
Revised date: 10/27/2021