**Remove the section in red.**

**Add your letterhead to the first page of the consent form.**

**Keep each section together on the same page: move it as needed.**

**Change font size for large print.**

**Version 5/2/16**

**This is a sample consent form.** OMIC policyholders are not required to use it. Be sure to review it and modify it to suit your actual practice.

**Document your informed consent discussion.** Documentation about the discussion and use of a procedure-specific consent form help defend you against allegations of lack of informed consent.

**Offer the patient a copy** **of your consent form**. Encourage the patient to read it again at home with his or her family, and to call with any questions.

**This version of the Ozurdex consent form is written using “plain language” principles.**

The goal is to make the document easy for your patients to understand. Patients report having a difficult time reading a consent document when it defined the various diseases that a drug is used to treat. We, therefore, removed disease names from the form. Instead, the form now explains that Ozurdex is used to treat the growth of blood vessels in the eye and swelling in the back of the eye. You know your patients and can decide which type of form works best for your practice. You may decide to keep using your current consent form.

**Informed consent for Ozurdex (dexamethasone) implant**

Ophthalmologists (eye surgeons) treat some types of eye problems with a medication called Ozurdex. Ozurdex can help decrease vision loss due to two types of eye problems:

1. swelling in the back of the eye (macular edema)
2. swelling of the middle layer of the eye without infection (uveitis)

Ozurdex is given by an injection (shot) into the back of your eye. The ophthalmologist may put eye drops to enlarge the pupil (black circle) in the center of your eye to see the back of your eye clearly. Next, the ophthalmologist will numb your eye as much as possible so that you do not feel pain. Then the ophthalmologist injects the Ozurdex implant into the back part of your eye. The implant does not need to be removed. It slowly melts (dissolves) and releases the medicine. Your ophthalmologist will tell you if you need another Ozurdex implant.

You may have some minor problems right after the injection. Your eye may be irritated and make a lot of tears for a few hours. The white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye. It will not change how well you see. It will usually clear up in about one or two weeks.

**Tell the ophthalmologist right away if you notice any other problems after the injection.** Problems can include an eye infection, eye pain, blurry or decreased vision, being extra sensitive to light, eye redness, and pus or other discharge coming from the eye. You can help prevent or reduce these problems:

* Do not rub your eyes or go swimming for 3 days after each injection.
* Call your ophthalmologist right away if you notice any of these problems.
* Keep all appointments with your ophthalmologist.

**Benefits (how this medication can help).** The goal is to prevent more vision loss. But Ozurdex may not bring back vision loss that happened before treatment.

**Alternatives (choices and options).** Ozurdex is not the only option. Your other treatment choices may include:

* No treatment. If you decide not to have treatment, then your eye problems can get worse. You could have more vision loss or even blindness.
* Medications approved by the Food and Drug Administration (FDA) for treating your type of eye problem.
* Other medications approved by the FDA for a different condition.
* Your ophthalmologist will tell you how these medications could help and the risks (problems) they might cause.

**Risks (problems this medication may cause).** As with all medications, there are risks from having an Ozurdex implant in the eye. These risks can cause vision loss or blindness. Your ophthalmologist cannot tell you about every risk. Here are some common or serious ones:

* Ozurdex might not improve your vision. Your vision may get worse.
* Ozurdex injections can cause other eye problems such as:
  + an eye infection
  + glaucoma (high eye pressure)
  + cataracts (clouding of the eye’s lens)
  + detached retina (the light-sensitive part of the back of your eye might get pulled off)
  + hypotony (low eye pressure)
  + retina or cornea damage
  + bleeding within the eye.
* Eye problems from Ozurdex can appear days, weeks, months, or even years after your injection. The costs to treat these are not included in the fee you pay for the Ozurdex injection.

**By signing below, you consent (agree) that:**

* You read this informed consent form or had it read to you.
* The ophthalmologist or staff member explained that you have swelling in the back of your eye or the middle of your eye.
* You will come back within 1 to 2 months after each injection to have the pressure in your eye checked.
* The ophthalmologist or staff member answered your questions about using Ozurdex to treat your eye problem.
* You consent to keep having Ozurdex injections. You will get injections unless you tell your ophthalmologist that you no longer want the medication or your eye problems change so much that there are new risks and benefits to discuss with the ophthalmologist.

**I want the ophthalmologist to inject the Ozurdex implant in:**

* **\_\_\_\_\_\_\_ my right eye**
* **\_\_\_\_\_\_\_ my left eye**
* **\_\_\_\_\_\_\_ both eyes.**

Patient (or person authorized to sign for patient) Date