This form is intended as a sample. It does not constitute the standard of care nor does it provide legal advice. It contains the information OMIC recommends the surgeon personally discuss with the patient.

**How to use this sample**

* Please modify it to fit your practice.
* **Delete this instruction box.**
* Add your letterhead to the first page of the consent form.
* Change font size if necessary.

**After the patient signs the form**

* Give the patient a copy of the signed form.
* Send a copy to the hospital or surgery center as verification that you have obtained informed consent.
* Keep the original in the patient’s medical record.

**Version** 11/10/2023

 **[Your Letterhead]**

**Informed Consent for Intravitreal Injection of IZERVAY™ (Avacincaptad pegol) Treatment for Geographic Atrophy, a form of Dry Age-Related Macular Degeneration**

**How IZERVAY™ treats your condition**

You have been diagnosed with geographic atrophy, an advanced form of dry age-related macular degeneration (AMD). Patients with geographic atrophy generally lose vision due to the death of cells in the macula (the center of the light-sensitive tissue at the back of your eye called the retina). The regions of dead cells are called geographic atrophy lesions.

Your ophthalmologist is recommending treatment of a drug called IZERVAY™ (Avacincaptad pegol), which may be able to slow down the growth of geographic atrophy lesions.

**Benefits (how this medication can help)**

The goal of using IZERVAY™ is to slow down the growth of the geographic atrophy lesion and prevent more vision loss. IZERVAY™ will not reverse geographic atrophy or bring back vision loss that happened before treatment.

**How the injection is given**

IZERVAY™ is given by an intravitreal injection, an injection (shot) into the back of your eye (the vitreous cavity).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 will inject IZERVAY™ into the back of your eye. IZERVAY™ injections are given once a month.

**You may have some minor problems right after the injection**

* Your vision might be blurry right after the injection. Do not drive or use machines until your vision gets better.
* 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. This will clear up in a few days or a week.
* You might see floaters (shadows, spots, or small specks that float through your field of vision). Many people already have floaters. These new floaters may go away in a few days, or you may stop noticing them. Some floaters are drops of the oil that lubricates the syringe. These will not go away.

**Tell your ophthalmologist right away if you notice any of these problems after the injection, such as:**

* Signs of infection, which include eye pain, blurry or decreased vision, extra sensitivity to light, eye redness, and pus or other discharge coming from the eye.
* New or large floaters that do not go away.
* Flashing lights or decreased side vision with the floaters.

**You must follow these instructions**

You can help prevent or reduce the above problems by doing the following:

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

**Risks (problems this medication may cause)**

As with all medications, there are risks from getting IZERVAY™ injections in the eye. These risks can cause vision loss or blindness. Your ophthalmologist cannot tell you about every risk or complication that may occur. Here are some common and serious ones:

* + IZERVAY™ will not improve your vision. Your vision may still get worse.
	+ Izervay injections can cause other eye problems such as:
* An eye infection
* Detached retina (the light-sensitive part of the back of your eye might get pulled off)
* Cataracts (clouding of the eye’s lens)
* Glaucoma (increased eye pressure)
* Hypotony (reduced eye pressure)
* Retina or cornea damage
* Bleeding within the eye
* Inflammation inside the eye that can cause vision loss, pain, or redness
* In clinical trials, use of IZERVAY™ was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (abnormal new blood vessels forming in the area between the retina and the white part of the eye) (7% in IZERVAY™ group, and 4% in the control group by Month 12). The patients that developed the wet form of AMD received standard-of-care treatment with anti-VEGF (anti-vascular endothelial growth factor) injections. While a harmful effect on vision was not observed in patients that developed wet AMD compared to those that did not, we do not know if a harmful effect on vision may eventually be observed.

It is extremely important that you are aware of any symptoms that might indicate one of these complications and that you report these symptoms to your doctor right away. If your doctor is not accessible for any reason, you should contact another eye doctor in this office immediately or seek emergency medical attention. The symptoms to be aware of include:

* Signs of infection, which include eye pain, blurry or decreased vision, extra sensitivity to light, eye redness, and pus or other discharge coming from the eye.
* New or large floaters that do not go away.
* Flashing lights or decreased side vision with the floaters.
* Increased discomfort
* Worsening eye redness
* Increased number of floaters
* Eye problems from IZERVAY™ can appear days, weeks, months or even years after your injection. The costs to treat these problems are not included in the fee you have for the IZERVAY™ injection.

**Anesthesia**

**What type of anesthesia is used?**

An intravitreal injection is performed using topical or subconjunctival anesthesia.

With **topical anesthesia**, eye drops or gel are used to numb the eye, and you must be able to cooperate with the surgeon to make sure you do not move your eye during the procedure.

**Risks of topical anesthesia**

* Inadvertent injury to the eye by movement during the procedure
* Drooping of the eyelid
* Increased sensation during the procedure
* Betadine® or chlorhexidine eye drops are used to sterilize the eye prior to an injection to reduce the chance of infection. If you refuse these drops, there is a higher chance of infection, which can cause loss of vision or loss of the eye.

With **subconjunctival anesthesia**, anesthetic medicine is injected under a thin transparent tissue that covers the white of the eye and this numbs the eye for injection.

**Risks of subconjunctival anesthesia**

* Needle damage to the eyeball or optic nerve, which could damage vision
* Inadvertent injury to the eye by movement during the procedure
* Drooping of the eyelid
* Bleeding on the surface or inside of the eye

**Alternatives (choices and options)**

IZERVAY™ is not the only option. Your other treatment choices may include:

* No treatment. If you decide not to have treatment, your geographic atrophy may get worse and you could have more vision loss or even blindness.
* Other medications approved by the FDA for treating your type of eye problem. Your ophthalmologist will tell you how these medications could help and the risks (problems) they might cause.

**Consent to Treatment**

By signing below, you agree and consent to the following:

· Your ophthalmologist has discussed the information in this consent form with you, as well as the consequences of refusing treatment.

· You understand that it is impossible for the ophthalmologist to inform you of every possible complication that may occur.

· Your ophthalmologist has answered your questions to your satisfaction.

· You have been offered a copy of this document.

· You understand that, during the procedure, unforeseen complications may occur that require additional procedures, and you authorize such procedures to be performed.

· Your ophthalmologist has informed you that Betadine® is a proven effective method for surface cleaning of the eye and surrounding areas, which reduces the risk of infection. You understand and acknowledge that if you choose to refuse the use of Betadine®, it may increase the risk of infection with this procedure.

· You consent to keep having IZERVAY™ injections unless you tell your ophthalmologist that you no longer want the medication, or your eye problems or other relevant health issues change so much that there are new risks and benefits to discuss with the ophthalmologist.

· You understand the signs and symptoms to watch for after the injection and agree to report them to your ophthalmologist immediately.

· You understand the risks and benefits of, and alternatives to, receiving IZERVAY™ and accept the risks.

· You acknowledge that no guarantees our promises have been made to you about the results of any procedure or treatment.

· You agree to keep all appointments with your ophthalmologist.

I authorize my ophthalmologist to proceed with an intravitreal injection of IZERVAY™ (Avacincaptad pegol) in my:

**\_\_Left** eye \_\_**Right** eye \_\_**Both** eyes

at regular intervals, as needed.

Patient’s Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Patient Signature (or person authorized to sign for patient) Date

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Printed Name