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 physician personally discuss with the patient.

**How to use this sample**

* Please modify it to fit your actual practice.
* **Remove 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** 3/20/23

 **[Your Letterhead]**

**Informed Consent for Intravitreal Injection of Byooviz™ (ranibizumab-nuna)**

**How Byooviz™ treats your condition**

Ophthalmologists use a medication called Byooviz™to help decrease vision loss due to two types of eye problems:

1. The growth of harmful blood vessels in your eyes, known as vascular endothelial growth factor (VEGF)
2. Swelling in the back of the eye (macular edema)

Because you have [Condition], your ophthalmologist, [Name]**,** M.D., is recommending Byooviz™, an anti-VEGF medication.

**Byooviz**™ **is known as a “biosimilar”**

Biosimilar drugs are chemically changed medications that closely resemble an original drug. The portion of the biosimilar that has been changed is an inactive portion of the drug. A biosimilar is FDA-approved; however, it goes through an abbreviated pathway to approval. Byooviz™ is FDA-approved to be used in the eye for conditions such as age-related macular degeneration and diabetic macular edema.

Byooviz™ is a biosimilar for another anti-VEGF medication called Lucentis® (ranibizumab).

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

The goal of using Byooviz™ for eye problems is to prevent more vision loss. Byooviz™ may not bring back vision loss that happened before treatment.

**How the injection is given**

Byooviz™ is given by an injection (shot) into the back of your eye (the intravitreal cavity). Eye drops may be used to enlarge the pupil (black circle) in the center of your eye to allow your ophthalmologist to see the back of your eye clearly. Next, your eye will be numbed as much as possible so that you do not feel pain. Then the ophthalmologist will inject Byooviz™ into the back part of your eye. Most patients need Byooviz™ injections about every 4 weeks because its effect wears off over time. Your ophthalmologist will tell you how often you will need Byooviz™ injections.

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

* You may have increased eye pressure within 1 hour of an 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 a week.
* You might see small specks called floaters. 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 other problems after the injection, such as:**

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

**You must follow these instructions:**

* 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 listed above.
* Keep all appointments with your ophthalmologist.

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

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

* Byooviz™ might not improve your vision. Your vision may get worse.
* Byooviz™ injections can cause other eye problems such as:
	+ An eye infection
		- 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.
	+ Inflammation inside the eye that can cause vision loss, pain, or redness
	+ Detached retina (the light-sensitive part of the back of your eye might get pulled off)
	+ Cataract (clouding of the eye’s lens)
	+ Glaucoma (increased eye pressure)
	+ Hypotony (reduced eye pressure)
	+ Retina or cornea damage
	+ Bleeding within the eye
* Some patients taking this medication have had heart attack, stroke, or death. The FDA does not know if the medicine caused these problems. Patients with diabetes may have these problems more often. Tell your ophthalmologist if you have had a heart attack or stroke.
* Eye problems from Byooviz™ can appear days, weeks, months, or even years after your injection. The costs to treat these problems are not included in the fee you pay for the Byooviz™ 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

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)**

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

* No treatment. If you decide not to have treatment, your eye problems can quickly get worse. You could have more vision loss or even blindness.
* Other medications approved by the FDA for treating your type of eye problem.
* Other medications approved by the FDA for a different condition. Ophthalmologists use these medications “off-label” because they may be similar or even have a better effect compared to an FDA-approved medication.
* 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, and has answered your questions about using Byooviz™ to treat your eye problem.
* The ophthalmologist explained that you have harmful blood vessels or swelling in the back of your eye.
* You consent to keep having Byooviz™ 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 that it is impossible for the ophthalmologist to inform you of every possible complication that may occur.
* If any unforeseen condition arises in the course of the above procedure that, in the ophthalmologist’s judgment, calls for procedures in addition to or different from those now contemplated, you further request and authorize the ophthalmologist or their designees to do whatever they deem advisable.
* 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 understand the signs and symptoms to watch for after the injection and agree to report them to your ophthalmologist immediately.
* You understand and accept the risks and benefits of, and alternatives to, receiving Byooviz™.

I authorize my ophthalmologist to proceed with an intravitreal injection of Byooviz™(ranibizumab-nuna) 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