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 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** 4/13/2022

**Consent for Vabysmo™ (faricimab-svoa) Intravitreal Injection**

**Indications and possible benefits**

Vabysmo is a prescription medicine given by injection into the eye to treat adults with Neovascular (Wet) Age-related Macular Degeneration (AMD) and Diabetic Macular Edema (DME).

**Vabysmo is given by an injection (shot) into the back of your eye.** The eye surgeon may put in eye drops to enlarge the pupil (black circle) in the center of your eye to see the back of your eye clearly. Next, the eye surgeon will numb your eye as much as possible so that you do not feel pain. Then the eye surgeon will inject Vabysmo into the back part of your eye. Your eye surgeon will tell you how often you will need Vabysmo injections.

**Benefits (how this medication can help).** The goal of using Vabysmo for eye problems is to prevent more vision loss. Vabysmo may not bring back vision loss that happened before treatment.

**Alternatives (choices and options).** Vabysmo 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 quickly get worse. You could have more vision loss or even blindness.
* Other 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. Eye surgeons use these medications “off-label” because they can help slow the growth of harmful eye blood vessels and lessen swelling that decreases vision.
* Your eye surgeon 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 getting Vabysmo injections in the eye. These risks can cause vision loss or blindness. Your eye surgeon cannot tell you about every risk. Here are some common or serious ones:

* Vabysmo might not improve your vision. Your vision may get worse.
* Vabysmo injections can cause other eye problems, such as:
	+ an eye infection
	+ ocular inflammation (an immune response that can cause swelling, pain, or redness in the eye)
	+ detached retina (the light-sensitive part of the back of the eye pulls away from its normal position)
	+ cataracts (clouding of the eye’s lens)
	+ glaucoma (increased eye pressure)
	+ hypotony (reduced eye pressure)
	+ damage to the retina or cornea (the clear, protective, outer layer of the eye)
	+ bleeding within the eye
	+ Your eye may be irritated and make a lot of tears for a few hours.
	+ Your vision might be blurry right after the injection.
	+ You might see small specks called 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 if you have new or large floaters that do not go away.
* 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 eye surgeon if you have had a heart attack or stroke.
* Eye problems from Vabysmo 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 Vabysmo injection.

**Possible risks to a fetus (unborn child).** Medications taken during pregnancy can harm the fetus. The FDA has issued warnings about Vabysmo. Here is more information about those warnings:

* Animal studies have shown that high doses of Vabysmo injected intravenously weekly for 5 weekslead to an increased risk of fetal death and miscarriage.
* The FDA does not know if intravenous doses of Vabysmo can cause an increased risk of fetal death and miscarriage in humans.
* Vabysmo is given differently in humans. The human dose of these drugs is much, much smaller than what was given to the animals, and is given only once every four to eight weeks. The drugs are injected into the eye, not into the vein.
* If you are pregnant, or could become pregnant while on Vabysmo, your eye surgeon wants you to know about the FDA warning. The FDA states that women of childbearing age who are on drugs like Vabysmo and wish to avoid pregnancy should use an effective birth control method before the first dose, during treatment, and for at least three months after the last injection. Talk to your regular doctor about whether you need to use birth control while you are getting Vabysmo. Show your doctor this form.

**Possible risk for breastfeeding.** Many medications are transferred in human milk with the potential for absorption and adverse reactions in the breastfed child. There is no information regarding the presence of Vabysmo in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Women who are breastfeeding should consider the developmental and health benefits of breastfeeding along with the medical need for Vabysmo and the potential adverse effects on the breastfed child.

**PATIENT CONSENT**

I have read this form or someone has read it to me. The nature of my eye condition has been explained to me and the proposed treatment has been described. The risks, benefits, alternatives, and limitations of the treatment have been discussed with me. All of my questions have been answered.

I understand that Vabysmo was approved by the FDA to treat adults with Neovascular (Wet) Age-related Macular Degeneration (AMD) and Diabetic Macular Edema (DME). I wish to be treated with Vabysmo, and I am willing to accept the potential risks that my physician has discussed with me.

 Patient initials \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I will take all prescribed medications as ordered and will immediately contact my ophthalmologist if any of the following signs of infection or other complications develop: eye pain, blurry or decreased vision, sensitivity to light, eye redness, or discharge from the eye. I have been instructed NOT to rub my eyes or swim for three days after each injection. I will keep all post-injection appointments or scheduled telephone calls so my doctor can check for complications.

 Patient initials \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I acknowledge that Betadine is a proven effective method for surface cleaning of the eye and surrounding areas, which can reduce the risk of infection. I understand and acknowledge that if I choose to refuse the use of Betadine it may increase the risk of infection with this procedure.

 Patient initials \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I hereby authorize Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to administer the intravitreal injection of

Vabysmo in my \_\_\_\_\_\_\_\_\_ (state “right” or “left”) eye at regular intervals as needed.

This consent will be valid unless I revoke it by refusing an injection or my condition changes to the point that the risks and benefits of this medication for me are significantly different.

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

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Printed Name