

INFORMED CONSENT FOR AVASTIN™ (BEVACIZUMAB) INTRAVITREAL INJECTION

INDICATIONS

- ♦ Age-related macular degeneration (AMD) is the leading cause of blindness in people over 50 years of age. There are two types of macular degeneration: dry and wet. In the “wet” form of AMD, abnormal blood vessels grow in the back of the eye. Sometimes these vessels leak blood or fluid that causes blurred or distorted vision. Without treatment, vision loss may be quick and severe.
- ♦ There are other eye conditions that cause loss of vision due to abnormal growth of blood vessels in the back of the eye. These can occur even in young patients, and include, but are not limited to, conditions such as high myopia (nearsightedness), histoplasmosis, angioid streaks, and eye injury. Sometimes there is no known reason for the abnormal blood vessels. Without treatment, vision loss may be quick and severe.
- ♦ Refractory macular edema, or swelling around the macula, is edema that affects vision but does not respond adequately to the usual treatment methods. It can occur with conditions such as central retinal vein occlusion and diabetic retinopathy. Without effective treatment, vision loss could progress and become permanent.

POSSIBLE BENEFITS AND “OFF-LABEL” STATUS

Avastin™ was not initially developed to treat your eye condition. Based upon the results of clinical trials that demonstrated its safety and effectiveness, Avastin™ was approved by the Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer. As a condition of approval, the manufacturer produced a “label” explaining the indications, risks, and benefits. The label explains that Avastin™ works by blocking a substance known as vascular endothelial growth factor or VEGF. Blocking or inhibiting VEGF helps prevent further growth of the blood vessels that the cancer needs to continue growing.

Once a device or medication is approved by the FDA, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects. Ophthalmologists are using Avastin™ “off-label” to treat AMD and similar conditions since research indicates that VEGF is one of the causes for the growth of the abnormal blood vessels that cause these conditions. Some patients treated with Avastin™ had less fluid and more normal-appearing maculas, and their vision improved. Avastin™ is also used, therefore, to treat macular edema, or swelling of the macula. Recently, a medication similar in function and designed for intravitreal administration was approved by the FDA for the treatment of AMD.

POSSIBLE LIMITATIONS AND ADMINISTRATIONS

The goal of treatment is to prevent loss of vision. Although some patients have regained vision, the medication may not restore vision that has already been lost, and may not ultimately prevent further loss of vision caused by the disease. After the pupil is dilated and the eye is numbed with anesthesia, the medication is injected into the vitreous or jelly-like substance in the back chamber of the eye. Avastin™ is administered by an injection into your eye as needed at regular intervals (about every four to six weeks); your ophthalmologist will tell you how often you will receive the injection, and for how long.

ALTERNATIVES

You do not have to receive treatment for your condition, although without treatment, these diseases can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available.

At present, there are three FDA-approved treatments for neovascular age-related macular degeneration. The first two are photodynamic therapy with a drug called Visudyne™ and injection into the eye of a drug called Macugen™. Although both of these treatments have been proved to slow down the rate of visual loss, most people do not get back better vision. The third medication, Lucentis™ is similar to Avastin™. Your doctor will discuss with you the benefits and risks associated with these other choices of treatment. In addition to the FDA-approved medications, some ophthalmologists use intravitreal Triamcinolone Acetonide –a long-acting cortisone-like drug- “off-label” to treat eye conditions like yours.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Complications when Avastin™ is given to patients with cancer

When Avastin™ is given to patients with metastatic colorectal cancer, some patients experienced serious and sometimes life-threatening complications, such as gastrointestinal perforations of wound healing complications, hemorrhage, arterial thromboembolic events (such as stroke or heart attack), hypertension, proteinuria, and congestive heart failure.

Patients who experienced these complications not only had metastatic colon cancer, but were also given 400 times the dose you will be given, at more frequent intervals, and in a way (through and intravenous infusion) that spread the drug throughout their bodies.

Risk when Avastin™ is given to treat patients with eye conditions

Ophthalmologists believe that the risk of these complications for patients with eye conditions is low. Patients receiving Avastin™ for eye conditions are healthier than the cancer patients, and receive a significantly small dose, delivered only to the cavity of their eye. While there are no FDA-approved studies about the use of Avastin™ in the eye that prove it is safe and effective, Lucentis™, a similar drug, was recently approved for AMD. One study of patients who received Avastin™ through an intravenous infusion reported only a mild elevation in blood pressure. Another study of patients treated like you will be with intravitreal Avastin™ (that is, Avastin™ injected into the eye) did not have these elevations or other serious problems seen in the patients with cancer.

However, the benefits and risks of intravitreal Avastin™ for eye conditions are not fully known. In addition, whenever a medication is used in a large number of patients, a small number of coincidental life-threatening problems may occur that have no relationship to the treatment. For example, patients with diabetes are already at increased risk for heart attack and strokes. If one of these patients being treated with Avastin™ suffers a heart attack or stroke, it may be caused by the diabetes and not the Avastin™ treatment.

Known risks of intravitreal eye injections

Your condition may not get better or may become worse. Any or all of these complications may cause decreased vision and/or have a possibility of causing blindness. Additional procedures may be needed to treat these complications. During the follow up visits or phone calls, you will be checked for possible side effects and the results will be discussed with you.

Possible complications and side effects of the procedure and administration of Avastin™ include but are not limited to retinal detachment, cataract formation (clouding of the lens of the eye), glaucoma (increased pressure in the eye), hypotony (reduced pressure in the eye), damage to the retina or cornea (structures of the eye), and bleeding. There is also the possibility of an eye infection (endophthalmitis). You may receive eye drops with instructions on when to use them to reduce the possibility of this occurring. Any of these rare complications may lead to severe, permanent loss of vision.

Patients receiving an injection of Avastin™ may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, and povidone-iodine drops). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances.

PATIENT RESPONSIBILITIES

I will **immediately** contact my **ophthalmologist** if any of the following signs of infection or other complications develop: pain, blurry or decreased vision, sensitivity to light, redness of the eye (compared to immediately after the injection), 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

Although the likelihood of serious complications affecting other organs of my body is low, I will **immediately** contact my **primary care physician** or go to the emergency room if I experience abdominal pain associated with constipation and vomiting, abnormal bleeding, chest pain, severe headache, slurred speech, or weakness on one side of the body. As soon as possible, I will also notify my **ophthalmologist** of these problems.

⇒ _____ Patient initials

I will inform my **ophthalmologist** if I need to have any surgery, and I will inform **any other surgeon, including dentists**, that I am on a medication that needs to be stopped before I can have surgery.

⇒ _____ Patient initials

PATIENT CONSENT

The above explanation has been read by/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 my questions have been answered.

♦I understand that Avastin™ was approved by the FDA for the treatment of metastatic colorectal cancer, and has not been approved for the treatment of eye conditions. Nevertheless, I wish to be treated with Avastin™, and I am willing to accept the potential risks that my physician has discussed with me.

⇒ _____ Patient initials

♦I hereby authorize Dr. _____ to administer the intravitreal injection of Avastin™ in my _____ (state “right” or “left”) eye at regular intervals as needed. This consent will be valid until I revoke it or my condition changes to the point that the risks and benefits of this medication for me are significantly different.

⇒ _____	_____
Patient’s Signature	Date
_____	_____
Witness’s Signature	Date
_____	_____
Physician’s Signature	Date

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If your insurance/Medicare doesn't pay for Intravitreal Avastin Injection(s), you may have to pay.

Medicare/Private Health Insurance does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare/your insurance may not pay for the intravitreal Avastin Injection below.

Procedure	Reason May Not Pay:	Estimated Cost:
Intravitreal Avastin Injection procedure 67028 drug supply J9035	Medicare and private health insurance classify Intravitreal Avastin Treatment as off-label or investigational for all ophthalmic diagnosis'	\$1,029.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **intravitreal Avastin Injection** listed above.
Note to Medicare beneficiaries: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTIONS: Check only one box. We cannot choose a box for you.

OPTION 1. I want the **intravitreal Avastin Injection** listed above. You may ask to be paid now, but I also want Medicare/my insurance billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN) or Explanation of Benefits (EOB). I understand that if Medicare/my insurance doesn't pay, I am responsible for payment, but I can appeal to Medicare/my insurance by following the directions on the MSN/EOB. If Medicare/my insurance does pay, you will refund any payments I made to you, less co-pays or deductibles.

OPTION 2. I want the **intravitreal Avastin Injection** listed above, but do not bill Medicare/my insurance. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare/my insurance is not billed.

OPTION 3. I don't want the **intravitreal Avastin Injection** listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare/my insurance would pay.

Additional Information:

This notice gives our opinion, not an official Medicare/payer decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048) or your private health insurance carrier. Signing below means that you have received and understand this notice. You also receive a copy.

Signature: _____

Date: _____