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INFORMED CONSENT FOR LUCENTIS™ (RANIBIZUMAB) 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. Central Retinal Vein Occlusion and Branch Retina Vein Occlusion are also diseases that cause macular fluid and visual loss.

POSSIBLE BENEFITS, LIMITATIONS, AND ADMINISTRATION

Lucentis™ works by inhibiting the growth of the abnormal blood vessels that cause AMD. It is also used to treat swelling of the macula due to AMD. The goal of treatment is to prevent further 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. Lucentis™ is administered by an injection into your eye as needed at regular intervals (about every four 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, AMD can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are two other FDA-approved treatments for neovascular AMD: photodynamic therapy with a drug called Visudyne™ and injection into the eye of a drug called Macugen™. Although both of these treatments have been proven to

slow down the rate of visual loss, most people do not get back better vision. In addition to the FDA-approved medications, some ophthalmologists use other medications that were not specifically approved for use in the treatment of AMD, but which have shown some benefit. The two medications used this way are intravitreal Kenalog™—a long-acting cortisone-like drug, and Avastin™—a similar drug to Lucentis™.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Complications of Lucentis™ in other body parts

A small number of patients (less than 4%) experienced blood clots (arterial thromboembolic events such as heart attack or stroke) after administration of Lucentis™. One preliminary study suggests that patients with a history of a stroke may be at greater risk for another stroke if they are given higher doses of Lucentis™. If you have had a stroke, please discuss this issue with your physician. 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 attacks and strokes. If one of these patients being treated with Lucentis™ suffers a heart attack or stroke, it may be caused by the diabetes and not the Lucentis™ treatment.

Known risks of intravitreal eye injections

Your condition may not get better or may become worse. Any or all of the following 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 of the procedure and administration of Lucentis™ 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. 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 such as small specks in the vision.

PATIENT RESPONSIBILITIES

I will immediately contact my **ophthalmologist (eye surgeon)** 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 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 hereby authorize Dr. _____ to administer the intravitreal injection of Lucentis™ 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

