New England Retina Consultants, PC
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Name_____ DOB_____

INFORMED CONSENT FOR LUCENTIS™ (RANIBIZUMAB) INTRAVITREAL INJECTION

INDICATIONS

Lucentis™ is approved by the Food and Drug Administration (FDA) to treat two eye conditions. The first is age-related macular degeneration (AMD), which 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. Lucentis™ is also approved to treat swelling (macular edema) following retinal vein blockage or occlusion (RVO).

POSSIBLE BENEFITS, LIMITATIONS, AND ADMINISTRATION

Lucentis™ works by inhibiting the growth of the abnormal blood vessels that cause AMD; it also decreases swelling of the macula. 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. 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 and macular edema from RVO can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are other FDA-approved treatments for neovascular AMD: photodynamic therapy with a drug called Visudyne™ , and injection into the eye of a drug called Macugen™ or a steroid called Triescence™ or Trivaris™. Although 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 Avastin™—a similar drug to Lucentis™—for the treatment of AMD or macular edema. There is another approved drug for RVO called Ozurdex™.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Complications of Lucentis™

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.

Although not common, some patients have had eye- and non-eye related blood clots (heart attacks, strokes, and death). If you have had a stroke or heart attack, you should 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.

Possible complications of the procedure and administration of Lucentis™ include but are not limited to retinal detachment, a serious infection (endophthalmitis), swelling within the eye (inflammation), 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. 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. The most common side effects to your eye are increased redness in the whites of your eye (conjunctival hemorrhage), eye pain, small specks in vision (floaters), and the feeling that something is in your eye. The most common non-eye-related side effects are nose and throat infections, headache, and lung (respiratory) infections.

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 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 EYE

_____ _____ _____
Patient's Signature Date EYE