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INFORMED CONSENT FOR EYLEA™ (AFLIBERCEPT) INJECTION FOR INTRAVITREAL USE

INDICATIONS

EYLEA™ is approved by the Food and Drug Administration (FDA) to treat Neovascular (Wet) 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.

POSSIBLE BENEFITS, LIMITATIONS, AND ADMINISTRATION

EYLEA™ 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.

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. EYLEA™ is administered by an injection into your eye as needed at regular intervals (every four weeks for the first three months, then once every eight 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, wet macular degeneration 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 Lucentis™, and injection into the eye of a drug called Visudyne™ or Macugen™. 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.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Complications of EYLEA™

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 non-eye related adverse events, for example, 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 EYLEA™ suffers a heart attack or stroke, it may be caused by the diabetes and not the EYLEA™ treatment.

Possible complications of the procedure and administration of EYLEA™ include but are not limited to eye related adverse events such as 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, cataract, vitreous detachment, small specks in vision (floaters), increased intraocular pressure, and the feeling that something is in your eye.

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 EYLEA™ 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