

PATIENT _____ DATE _____ OD OS

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.

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 MAD. 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™ and others had high blood pressure. There is no evidence that Lucentis™ caused these complications. 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 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

Patient's Name:

Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these health care items or services.

We expect that Medicare will not pay for the item(s) or service(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for –**

Items or Services:

1. Intravitreal Lucentis (ranibizumab 0.5mg) [drug supply]
2. Intravitreal injection of pharmaceutical [drug delivery procedure]

Because:

Lucentis (ranibizumab 0.5 mg) was approved by the Food and Drug Administration (FDA) for the treatment of exudative age-related macular degeneration on 30 June 2006. Treatment of macular edema and/or other ophthalmic indications are considered "off-label" use of the drug and therefore NOT covered by Medicare or other private health insurance. Although "approved" you agree if Medicare or your private health insurance denies payment for the drug and/or administration of the drug you shall be financially responsible.

The purpose of this form is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these items or services will cost you (**Estimated Cost: \$ _____**), in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE ONE OPTION. CHECK ONE BOX. SIGN & DATE YOUR CHOICE.

Option 1. YES. I want to receive these items or services.

I understand that Medicare will not decide whether to pay unless I receive these items or services. Please submit my claim to Medicare. I understand that you may bill me for items or services and that I may have to pay the bill while Medicare is making its decision. If Medicare does pay, you will refund to me any payments I made to you that are due to me. If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have. I understand I can appeal Medicare's decision.

Option 2. NO. I have decided not to receive these items or services.

I will not receive these items or services. I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay.

Date

Signature of patient or person acting on patient's behalf

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.