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Avastin (bevacizumab) intravitreal injection **Information for Patients**

Ophthalmology Departments Lincoln County Hospital Pilgrim Hospital www.ulh.nhs.uk

Aim of the leaflet

The aim of this leaflet is to provide information on Avastin (bevacizumab) intravitreal injections for the treatment of AMD.

Introduction

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 at the macula. The macula is important in the type of eyesight you use for reading and recognizing faces. 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) 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 oedema, or swelling around the macula, 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 develop and become permanent.

If you have any questions about any of the information contained in this leaflet please contact:

Wet AMD service coordinator on 01522 573566 Monday to Friday 9am to 5pm

Other useful contact details

Clinic 8, Lincoln County Hospital 01522 512512 ext 2457

Monday to Friday 9am to 5pm

Royle Eye Department, Pilgrim Hospital

01205 445626

Monday to Thursday 8am to 8pm, Friday 9am to 5pm

External sources of information

The following websites have further information:

Macular Society

Tel: 0845 241 2041 www.maculardisease.org

Royal National Institute of Blind People

Helpline: 0303 123 9999

www.rnib.org.uk

You should NOT rub your eyes or swim for three days after each injection. You should keep all post-injection appointments or scheduled telephone calls so your eye doctor can check for complications.

Although the likelihood of serious complications affecting other organs of your body is low, you should **immediately** contact your GP **or go to Accident and Emergency** if you experience:

- abdominal pain associated with constipation and vomiting
- abnormal bleeding
- chest pain
- severe headache
- slurred speech
- weakness on one side of the body

As soon as is reasonably possible, you should also notify your eye doctor of these problems.

Contact details

If you have any queries or concerns about this treatment please speak to your eye doctor during your consultation.

What is '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 licensed for the treatment of colorectal cancer. As a condition of the licence, 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 has been licensed, doctors 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. Eye doctors 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 vessels that cause these conditions.

What are the benefits of Avastin?

Some patients treated with Avastin had less fluid and more normal-appearing maculae and their vision improved. Avastin is also used, therefore, to treat macular oedema, or swelling of the macula. Recently, a medication similar in function and designed for intravitreal administration was licensed for the treatment of AMD.

What are the limitations with this treatment?

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.

How is this treatment carried out?

After the pupil is dilated and the eye is numbed with local anaesthesia, the medication is injected into the vitreous (the jelly-like substance in the back chamber of the eye). Avastin is given by an injection into your eye as needed at regular intervals (about every four to eight weeks) based on the control of the condition; your ophthalmologist will tell you how often you will receive the injection and for how long.

Patients receiving an injection of Avastin may experience less severe side effects related to the preparation for the injection (eyelid speculum, anaesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anaesthetic). These side effects may include:

- eye pain
- bloodshot eye (subconjunctival haemorrhage)
- irregularity or swelling of the cornea
- inflammation of the eye
- visual disturbances such as small specks in the vision

Patient responsibilities

You should contact an eye doctor as instructed in the accompanying advice sheet if any of the following signs of infection or other complications develop:

- increasing pain
- increasing blurring vision or decreasing vision
- increasing painful redness of the eye (compared to immediately after the injection)
- increasing discharge from the eye

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)
- increased pressure in the eye (glaucoma)
- reduced pressure in the eye (hypotony)
- damage to the retina or cornea (structures of the eye)
- 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.

Are there any alternatives to this treatment?

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 licensed treatments for wet age -related macular degeneration. They are:

- Photodynamic therapy with a drug called Visudyne
- Injection into the eye of a drug called Macugen
- Injection into the eye of a drug called Lucentis
- Injection into the eye of a drug called Eylea

Your doctor will discuss the benefits and risks associated with these other choices of treatment with you. In addition to the licensed medications, some eye doctors use intravitreal Kenalog - a long-acting steroid drug off-label to treat eye conditions like yours.

What are the complications from the medication and injection?

Complications when Avastin is given to patients with cancer

When Avastin was given to patients with colorectal cancer, some patients experienced serious and sometimes life-threatening complications, such as:

- gastrointestinal perforations or wound healing complications
- bleeding (haemorrhage)
- arterial thromboembolic events (such as stroke or heart attack)
- high blood pressure (hypertension)
- kidney problems

It is also important to note that patients who experienced these complications not only had colon cancer, but were also given 400 times the dose you will be given, at more frequent intervals and in a way (through an intravenous infusion or injection) that spread the drug throughout their bodies.

What are the risks when Avastin is given to treat patients with eye conditions?

Eye doctors 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 smaller dose, delivered only to the cavity of their eye.

While there are no studies approved by agencies that license drugs about the use of Avastin in the eye that prove it is safe and effective, Lucentis, a similar drug, is approved for AMD. One study of patients who received Avastin through an intravenous infusion reported only a mild increase in blood pressure.

Another study of patients treated with intravitreal Avastin (that is, Avastin injected into the eye) did not have these increases in blood pressure or the other serious problems seen in the patients with cancer.

However, the benefits and risks of intravitreal Avastin for eye conditions are not yet 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 attacks 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.