

Plaza Del Rio Eye Clinic, P.C.

Treatment for Wet Macular Degeneration

AVASTIN™ (BEVACIZUMAB) 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.
- 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), histoplasmosis, angioid streaks, 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 edema, or swelling around the macula, is edema that affects vision but does not respond adequately to the usual treatment methods. It can occur with conditions such as retinal vein occlusion (RVO) and diabetes (diabetic macular edema or DME). Without effective treatment, vision loss could progress and become permanent.

POSSIBLE BENEFITS AND "OFF-LABEL" STATUS

Avastin™ (bevacizumab) was not initially developed to treat your eye condition. Based upon the results of clinical trials that demonstrated its safety and effectiveness, Avastin™ (bevacizumab) was approved by the Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer. As a condition of approval, the manufacturer produced a "label" explaining the indications, risks, and benefits. The label explains that Avastin™ (bevacizumab) 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 is approved by the FDA, physicians 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. Ophthalmologists have used Avastin™ (bevacizumab) "off-label" to treat AMD and similar conditions since 2005. Indeed, research indicates that VEGF is one of the causes for the growth of the abnormal vessels that cause these conditions. Some patients treated with Avastin™ (bevacizumab) had less fluid and more normal-appearing maculas, and their vision improved. Avastin™ (bevacizumab) is also used, therefore, to treat macular edema, or swelling of the macula associated with central vein occlusion (CVO) and diabetic macular edema (DME).

POSSIBLE LIMITATIONS AND ADMINISTRATION

The goal of treatment is to prevent further loss of vision. Although many 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. Avastin™ (bevacizumab) 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, these diseases can lead to further vision loss and blindness, sometimes very quickly. Other forms of treatment are available. At present, there are four FDA-approved treatments for neovascular age-related macular degeneration (AMD). The first two are photodynamic therapy with a drug called Visudyne™ (verteporfin) and injection into the eye of a drug called Macugen™ (pegaptanib). Although both of these treatments have been proven to slow down the rate of visual loss, most people do not get back better vision. The other two medications, Lucentis™ (ranibizumab) and Eylea™ (aflibercept) are similar to Avastin™ (bevacizumab), and have been approved for AMD. Three drugs have been approved to treat edema associated with retinal vein occlusion (RVO): Lucentis™ (ranibizumab), Eylea™ (aflibercept), and Ozurdex™ (dexamethasone). Lucentis™ (ranibizumab) has also been approved for diabetic macular edema (DME). In addition to the FDA-approved medications, some ophthalmologists use triamcinolone acetonide, a long-acting cortisone-like drug (Kenalog™, Triesence™, or Trivaris™) to treat eye conditions like yours. Your doctor will discuss with you the benefits and risks associated with these other choices of treatment.

Risk when anti-VEGF drugs are given to treat patients with eye conditions

Avastin™ (bevacizumab) has been administered to hundreds of thousands of patients since 2005, and two similar drugs have been approved after clinical trials showed they were safe and effective. The results of the clinical studies and of "off-label" use indicate that the risk of serious complications like this for patients with eye conditions is low. Patients receiving anti-VEGF drugs such as Avastin™ (bevacizumab) for eye conditions are healthier than the cancer patients, and receive a significantly small dose, delivered only to the cavity of their eye.

There is, however, the possibility of arterial thromboembolic events (ATEs), defined as nonfatal stroke, nonfatal heart attack, and arterial death. 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, and the clinical trial conducted in order to approve one of the anti-VEGF drugs for diabetic edema showed that diabetic patients had slightly more deaths. There were not many deaths, and the cause was typical of patients with advanced diabetic complications. It is not clear, however, whether the drug or the diabetes caused the deaths.

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™ (bevacizumab) 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.

Patients receiving an injection of Avastin™ (bevacizumab) may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These 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.