INFORMED CONSENT FOR TREATMENT OF SYMPTOMATIC VITREOMACULAR ADHESION WITH INTRAVITREAL INJECTION OF JETREA® (OCRIPLASMIN)

WHAT IS SYMPTOMATIC VITREOMACULAR ADHESION AND HOW IS IT TREATED?

The retina, a light-sensitive tissue that lines the back of the eye, absorbs light and sends visual signals to the brain, where they are processed into images. The macula is a small, specialized area of the retina responsible for clear, detailed vision. The vitreous is a clear, jelly-like liquid that fills the inside of the eye between the lens in the front of the eye and the retina.

With age, the vitreous begins to liquefy and separate from the retina. For most people, this occurs without complication. Sometimes, the vitreous does not fully separate from the back of the eye and remains attached to the macula. This abnormal attachment is known as vitreomacular adhesion (VMA). If the VMA persists, pulling on the macula can occur and cause symptoms with your vision, known as symptomatic VMA. These symptoms may be distorted vision, blurred vision, or a defect in your central vision. VMA that goes untreated can lead to the development of further complications such as worsened vision, macular hole, and/or blindness.

JETREA® (ocriplasmin) is an FDA approved pharmacological treatment for symptomatic VMA. It is a clear, colorless solution that is injected into the vitreous of your eye. This medication is designed to dissolve the protein matrix that causes VMA.

ALTERNATIVES

You do not have to undergo treatment with JETREA®. Alternatives to injection with JETREA are explained below.

Until the availability of JETREA, the standard of care in the treatment of mild to moderate symptomatic VMA in patients has been “watchful waiting.” In symptomatic VMA patients with more significant vision loss, the standard of care is vitrectomy, which involves surgically removing the vitreous from the eye, thereby releasing the symptomatic VMA.

If you have symptomatic VMA needing the vitrectomy procedure and do not have it done, your symptomatic VMA can worsen, possibly leading to permanent vision loss.

HOW WILL THIS TREATMENT AFFECT MY VISION AND/OR CONDITION?

There is no guarantee that the injection with JETREA® will improve your condition. Sometimes it doesn’t work. In addition, this treatment and/or the injection procedure may cause some side effects. The injection procedure may cause intraocular inflammation, infection, or hemorrhage. It could also result
in eye pain or increased intraocular pressure. Sometimes it can make the problem worse, cause an injury, or create a new problem; if it does, this is called a complication. Complications can happen right away or not until days, months, or years later. You may need more treatment or surgery to treat the complications.

This document lists the major risks of this treatment with JETREA® to help you decide whether you are ready to accept the risks.

Possible complications and side effects of the procedure and administration of JETREA®

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.

- Decreased Vision- The majority of these decreases in vision were due to progression of the condition with traction and many required surgical intervention.
- Intraocular inflammation/ infection, intraocular hemorrhage and increased intraocular pressure (IOP). Most of the post-injection intraocular inflammation events were mild and transient.
- Potential for Lens Subluxation- (displacement or malpositioned lens within the eye)
- Dyschromotopsia- generally described as yellowish vision, some with electroretinograph (ERG) changes reported
- Retinal detachment or retinal tear
- Cataract formation (clouding of the lens of the eye)
- Hypotony (reduced pressure in the eye)
- Damage to the retina or cornea (structures of the eye)
- There is also the possibility of an eye infection (endophthalmitis)
- Patients may experience temporary visual impairment after receiving an intravitreal injection of JETREA

The most common adverse reactions (incidence 8% - 20%) with JETREA were vitreous floaters, conjunctival hemorrhage (bleeding within the outside lining of the eye), eye pain, photopsia (flashes of light), and blurred vision.

PATIENT RESPONSIBILITIES

I will immediately contact my ophthalmologist if any of the following signs of infection or other complications develop: eye becomes red, sensitive to light, painful, or develops a change in vision. I have been instructed NOT to rub my eyes or swim for three days after the injection. I will keep all post-injection appointments or scheduled telephone calls so my doctor can check for complications.
PATIENT’S ACCEPTANCE OF RISKS

I have read the above information (or it was read to me) and have discussed it with my physician. I understand that it is impossible for the physician to inform me of every possible complication that may occur. My physician has told me that results cannot be guaranteed and that more treatment or surgery may be necessary. By signing below, I agree that my physician has answered all of my questions and that I understand and accept the risks, benefits, and alternatives of receiving JETREA® for symptomatic VMA. I have been offered a copy of this document.

____________________________________________________________________________________
Patient Signature (or Person Authorized to Sign for Patient)  Date