OMIC OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

Risk Management Recommendations for Retisert™

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INSTRUCTIONS AND DISCLAIMER:

Please review the form, modify it to fit your actual practice, and add yourletterhead. Please offer the patient a copy. The form can be copied and sent to the hospital or ambulatory surgery center as verification of consent if the procedure will be performed there.

This sample consent form is intended as a sample only as a risk management service. It is not intended to constitute a standard of care or provide legal advice, and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted. This information is not intended to be a modification of the terms and conditions of your OMIC policy of insurance. Please refer to your OMIC policy for these terms and conditions.

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Risk Management Recommendations for Retisert™ (fluocinolone acetonide intravitreal implant)

- Patient selection
  - The following information and complete prescribing information for Retisert™ can be found at http://www.retisert.com/prescribing_information.pdf.
  - Retisert™ (fluocinolone acetonide intravitreal implant) 0.59 mg is a sterile implant surgically implanted into the posterior segment of the affected eye through a pars plana incision. It is approved for the treatment of chronic non-infectious posterior uveitis affecting the posterior segment of the eye. Any other use would be considered "off-label."
  - To determine if patients would benefit from Retisert™, conduct at least a thorough examination of the eye with a slit lamp microscope and ophthalmoscopy, and evaluate visual acuity and intraocular pressure. Blood work and other tests may be required to rule out underlying systemic disease or infection.
  - Retisert™ is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infections of the eye and fungal diseases of ocular structures, as well as patients with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.
  - Retisert™ has not been thoroughly studied in pregnant women. It should be

used during pregnancy *only if* the potential benefit justifies the potential risk to the fetus. Caution should be exercised when Retisert™ is implanted in nursing women as it is not known whether ocular administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.
    - The safety and effectiveness of Retisert™ in pediatric patients below the age of 12 years have not been established.
- Preparation of the implantation
    - "Drug Delivery Technology" can be located at http://www.retisert.com/professional_delivery.html.
    - The surgical procedure, demonstration video, and pre- and postoperative regimens are available at http://www.retisert.com/professional_procedure.html.
    - As with all intraocular surgery, sterility of the surgical field and Retisert™ should be rigorously maintained.
- Preventing, disclosing, and managing complications from intravitreal implantation
    - Retisert™ is associated with complications that require both medical and surgical management. Educate the patient about the warning signs of complications and how to contact you. Consider giving these instructions in writing.
    - Following implantation of Retisert™, nearly all patients will experience an immediate and temporary decrease in visual acuity in the implanted eye which lasts for approximately one to four weeks post-operatively. This decrease in visual acuity has been attributed to the surgical procedure itself. It is important to educate both patients and staff about this loss of vision.
    - The most common adverse events of implantation of Retisert™ include cataract progression and increased IOP. These complications should be anticipated and disclosed to the patient as part of the informed consent discussion.
        - Cataract surgery will be necessary to treat cataract progression.
            - Within an average post-implantation period of approximately 2 years, nearly all phakic eyes are expected to develop cataracts and require cataract surgery.
        - The surgeon should assess IOP or optic nerve perfusion as appropriate. The assessment should be documented in the medical record. Eye drops or filtering surgery may be necessary to lower IOP.
            - According to the prescribing information, within 34 weeks post-implantation, approximately 60% of patients will require IOP lowering medications to control intraocular pressure. Within an average post-implantation period of approximately two years, approximately 32% of patients are expected to require filtering procedures to control IOP.
    - In addition to the complications discussed above, Retisert™ can cause choroidal detachment, endophthalmitis, hypotony, exacerbation of intraocular inflammation, retinal detachment, vitreous hemorrhage, vitreous loss, and wound dehiscence.

- Documentation
  - Document both the decision-making process that led to choosing Retisert™ as the treatment for the patient and the informed consent discussion. Note results of earlier attempts at treatment (if applicable) and the results of diagnostic tests.
  - Note any complications from the surgery, how they were handled, and the discharge and follow-up instructions.
  - Document ongoing efforts to monitor for complications, especially the development of cataracts or elevated intraocular pressure, and measures taken to address the complications.

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, extension 641.