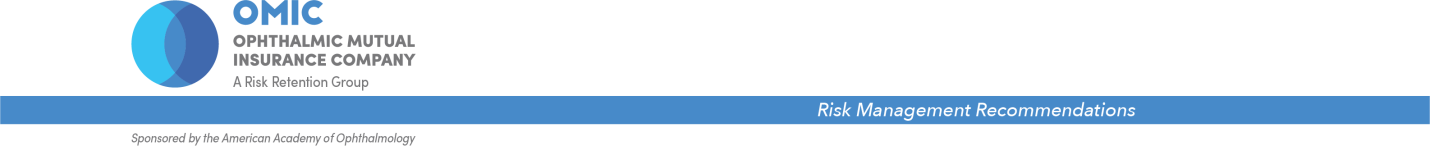
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**Intraocular Triamcinolone Acetonide**

**(KenalogTM or TriesenceTM)**

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**PURPOSE OF RISK MANAGEMENT RECOMMENDATIONS**

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology’s Preferred Practice Patterns, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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Steroids and their effect on the eye have been studied for nearly sixty years.[[1]](#footnote-1) For much of that time, ophthalmologists injected KenalogTM (triamcinolone acetonide or TA) off-label since no formulation of TA was approved by the Food and Drug Administration (FDA) for intraocular use. Preservative-free TriesenceTM (Alcon, Ft. Worth, TX) became available in 2007, and is approved to treat sympathetic ophthalmia, temporal arteritis, uveitis, ocular inflammatory conditions unresponsive to topical corticosteroids, and visualization during vitrectomy. Ophthalmologists use Triesence for other indications, and may use KenalogTM off-label, especially when manufacturing delays make TriesenceTM unavailable. Some ophthalmologists have contacted OMIC to inquire about the medicolegal consequences of “off-label” use of these two drugs.

The FDA has clarified that once it approves a device/medication, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific information and sound medical evidence, and maintain records of its use and effects.[[2]](#footnote-2) The FDA considers such use to be “the practice of medicine,” which it does not directly regulate. The FDA does, however, expect physicians to practice in a manner that is designed solely to insure the well-being of the individual patient. Accordingly, the FDA generally does not oversee or interfere with a physician's individual practice decisions unless a physician is himself marketing or selling a drug or device, acting as an investigator in clinical research, or gathering information about safety or efficacy.

In accordance with this FDA guidance, our Legal and Risk Management Departments recognize that “off-label” use of approved medications is a legal and necessary part of the practice of medicine. In the event of a lawsuit, ophthalmologists who are challenged about their choice of one medication over another will continue to rely upon expert witnesses, peer-reviewed literature, and well-documented efforts to provide quality care. Furthermore, OMIC feels that the ophthalmologist is in the best position to determine which medication would best serve the patient’s needs. Our professional liability policy thus provides coverage for such off-label use.

**Treatment selection**

* Determine what is in the best interests of the particular patient.
* Consider using the FDA-approved medication for the patient’s ophthalmic condition if it is available and covered by the patient’s insurance plan.
* Conduct and document pertinent diagnostic/monitoring tests, such as fluorescein angiogram and OCT, as part of the evaluation. If applicable, note lesion type, location, size, and presence of subretinal fluid.
* Document prior treatment efforts, if any, and the decision-making process that led to the choice of triamcinolone acetonide.

**Preparation of KenalogTM for intraocular use**

* Proper aseptic technique should be utilized during the preparation and administration of the injection.
* Many ophthalmologists use the commercially available form of KenalogTM and prepare it for intraocular use.[[3]](#footnote-3)
* Others choose to administer a preservative-free form that is usually prepared by a compounding pharmacy, a process that may introduce other risks. Compounding pharmacies (CFs) operate under Section 503A of the law and are governed by their state board of pharmacy. They must be in compliance with USP (United States Pharmacopeia) Chapter 797, which regulates the compounding, transportation, and storage of compounded sterile products (CSP). CFs require a patient-specific prescription.
* Credential the compounding pharmacy by asking for evidence of licensure in the state in which it is dispensing, and assurance that it maintains strict compliance with USP chapter 797 mandates.

**Preventing and managing complications from intravitreal injections of TA**

An expert panel reviewed published studies of intravitreal injection technique and monitoring, and released guidelines in 2014.[[4]](#footnote-4) Please see the article for full details.

* External infections
  + Postpone injection until active external infections, including blepharitis, have been treated and cleared, unless the benefits of injection clearly outweigh the risk of endophthalmitis.
* Povidone-iodine
  + Ensure that povidone-iodine (5%-10%) is the last agent applied to the intended injection site before injection.
    - If a gel anesthetic is used, apply povidone-iodine both before and after application of the gel.
  + Povidone-iodine may also be applied to the eyelids, including the eyelid margins and eyelashes.
    - Avoid eyelid scrubbing or expressing material from the meibomian glands.
  + Prevent contact of the eyelashes and eyelid margins with both the injection site and the injection needle after final application of povidone-iodine and especially during the actual injection. Use either a speculum or other technique, such as manual lid retraction.
* Aerosolized droplets
  + Reduce the spread of aerosolized droplets during the injection preparation and procedure.
  + Use a surgical mask or minimize speaking by the physician, assistants, and patients.
* Bilateral injections on the same day
  + Exercise caution when performing bilateral injections on the same day.
  + Consider the injection for each eye as a separate procedure.
  + Use separate site preparation, individual syringes, needles, etc.
  + Use a different medication batch if using a compounded medication such as Avastin.
* Patient monitoring and education
  + Monitor patients for symptoms suggestive of elevated IOP and endophthalmitis.
  + Instruct patients to contact you immediately if the eye becomes red, sensitive to light, painful, or develops a change in vision. Consider giving these instructions in writing.

**Informed consent discussion and documentation**

* Inform the patient of the known risks associated with the injection technique as well as the medication (please see the sample consent forms for [Kenalog](https://www.omic.com/kenalog-consent-form/) and [Triesence](https://www.omic.com/triesence-consent-form/)).
* Forewarn patients at particular risk for specific complications e.g., increased risk of infection in diabetics, increased risk of elevated IOP and worsening of glaucoma in patients who are steroid-responders or who have glaucoma.
* TriesenceTM off-label
  + Inform the patient that the drug was not approved for the condition they have, but that off-label use is a legal and necessary aspect of the practice of medicine.
* Kenalog TM off-label
  + Inform patients that Kenalog was not approved for intravitreal injection. Explain that the manufacturer has recommended against ophthalmic use, but that the FDA and attorneys have confirmed that ongoing use is legal as part of the “practice of medicine.”
  + Explain if you are using Kenalog during an FDA-declared drug shortage.
  + Inform the patient that one form of TA has been approved for use in the eye.

Treatment of both eyes on the same day

* Document your decision-making process in the medical record.
* Inform the patient of the possibility of vision-threatening complications in both eyes.
* Explain the measures you will take to reduce the risk of infection (i.e., you will use a new syringe, needle, etc.).
* Obtain consent for injections in both eyes on the same day.
* Ensure that the patient has a ride home before administering the injections.

Documentation

* Document the diagnostic process as well as the decision-making process that led to choosing the particular drug as the treatment for the patient. Note results of earlier attempts at treatment and the results of diagnostic tests.
* Evaluate and document the continued need, effectiveness, and safety of the medication prior to each injection.
* Note the dose, lot number of the vial, any reactions to the injection and how they were handled, and the discharge and follow-up instructions.
* Document efforts to monitor for and respond to complications.
* Document referrals to sub-specialists, and place a copy of the consultation letter in the medical record.
* Document all communication to and from the patient, even if it occurs after a sub-specialist has taken over the care.

**OMIC policyholders are encouraged to contact our confidential Risk Management Hotline for assistance. Please call 800.562.6642, option 4 or email us at** [**riskmanagement@omic.com**](mailto:riskmanagement@omic.com)**.**

1. Lewis, Richard A, MD. Intravitreal KenalogTM and Glaucoma. *Glaucoma Today*. 2005. <https://glaucomatoday.com/articles/2005-mar-apr/0305_06.html>. Accessed 6/26/20. [↑](#footnote-ref-1)
2. Information Sheets. Guidance for Institutional Review Boards and Clinical Investigators.1998 Update “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices>. Accessed 6/25/20. [↑](#footnote-ref-2)
3. Gallemore RP, Boyer DS. Intravitreal Kenalog. Eye Net June 2020. <https://www.aao.org/eyenet/article/intravitreal-kenalog-injections>. Accessed 6/25/20. [↑](#footnote-ref-3)
4. Avery RL et al. Intravitreal Injection Technique and Monitoring. Updated Guidelines of an Expert Panel. *Retina*. 2014: 34, number 12, S1-S18. [↑](#footnote-ref-4)