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**DURYSTA (bimatoprost implant):**

**Recommendations and sample consent form**

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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.

**Version 8/4/20**

The FDA approved the DURYSTA implant in June, 2020 for the treatment of open-angle glaucoma. These risk management recommendations address the risk of endothelial cell loss (ECL), and the sample consent form helps educate patients about the risks and benefits.

**Endothelial cell loss (ECL)**

During the clinical trials, an ophthalmologist implanted DURYSTA every 4 months for a total of 3 implants per eye. The implant was intended to replace eye drops for 4 to 6 months, but some patients had ongoing effect for up to 24 months.

The FDA prescribing label noted that between 5% to 10% of patients in the clinical trials experienced ECL. This concern about ECL led the FDA to focus on this in 2 of the warnings on the label:

* “Endothelial Cell Loss. Due to possible corneal endothelial cell loss (ECL), administration of DURYSTA should be limited to a single implant per eye without retreatment.”
* “Corneal Adverse Reactions. DURYSTA has been associated with corneal adverse reactions and risks are increased with multiple implants. Use caution in patients with limited corneal endothelial reserve.”

While the implant is currently approved for single use, Phase III clinical trials to evaluate retreatment are ongoing.

**Risk/benefit analysis**

A single implant will substitute for eye drops for about 6 months of medication. Vision loss from ECL (and other possible complications) must be weighed against the benefit of this period of drop replacement. Some ophthalmologists may choose to implant DURYSTA more than one time per eye, despite the warnings. Per the FDA, this would increase the risk of ECL. Not all ophthalmologists have the equipment needed to evaluate and monitor endothelial cell counts. Without evidence of such an evaluation and monitoring, placing more than one implant per eye may be difficult to defend. The long-term risk of ECL from implants is unknown.

**OMIC position on “off-label” use**

There are no underwriting conditions of coverage or restrictions that apply to this medication (the only medications with such conditions are anti-VEGF agents used to treat ROP). OMIC has consistently supported off-label use and encouraged our policyholders to use their professional judgment on which medications to use for their patients.

**Informed consent**

Ophthalmologists who feel it is in their patient’s best interest to implant more than one DURYSTA per eye should obtain informed consent for each implant. Explain that the FDA approved only one treatment for each eye because of possible ECL loss. Share with the patient why you feel more than one implant is indicated. There is sample language at the end of this document that should be added to the consent form for retreatment.

**THIS IS A SAMPLE FORM: REVIEW AND REVISE AS NEEDED.**

**Replace this section with your letterhead.**

**Increase font size for large print as needed.**

**Version 8/4/20**

**DURYSTA (bimatoprost implant)**

You have glaucoma. Glaucoma is a disease defined by optic nerve damage. The optic nerve connects the eye to the brain. Fluid imbalance or eye pressure problems damage the nerve. Glaucoma slowly gets worse over time and cannot be reversed. If it is not treated, it causes a painless loss of eyesight. In some cases, it can lead to blindness.

**Your ophthalmologist (eye surgeon) recommends treating your glaucoma with the DURYSTA implant.** The implant contains a medication called bimatoprost that has been used for a long time to help lower eye pressure. The implant stays in your eye and releases the medicine for about 4 to 6 months while it slowly dissolves. The ophthalmologist will numb the eye so that you do not feel pain. The ophthalmologist will then use a microscope to carefully inject the implant into the anterior chamber (front part of the eye). You must remain upright (sitting or standing) for 1 hour after the injection.

**Benefits (how DURYSTA might help).** The purpose of the medication is to lower your eye pressure and help you keep the vision that you have now. It will not bring back the vision you may have already lost from glaucoma.

**Alternatives (choices and options).** The best choices for glaucoma treatment are those that lower eye pressure with the fewest risks to eyesight and overall health.

* Usually eye drop medications or laser surgery are used first. Often, multiple medications are needed to get the desired pressure level.
* If medications and laser treatment do not work well enough, or if patients have trouble using eye drops because of cost, side effects, and other difficulties, then glaucoma surgery is required. There are many types of glaucoma surgery.
* You can decide to have no treatment. Without treatment, your glaucoma will get worse and you will lose more vision. You may even go blind.

**You may have some minor problems right after the injection.**

* Your vision might be blurry right after the injection. Do not drive or use machines until your vision gets better.
* Your eye may be irritated and make a lot of tears for a few hours.
* The white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye. It will not change how well you see. This will clear up in a few days or a week.

**Tell the ophthalmologist right away if you notice any other problems after the injection.** Call if you have eye pain, blurry or decreased vision, extra sensitivity to light, eye redness, or pus or discharge coming from the eye.

**Risks (problems DURYSTA can cause).** There are risks with the medication, the injection, and the implant. While the ophthalmologist cannot tell you about every risk, here are some of the most common and serious ones:

* Risks from the medication
	+ Failure to control eye pressure, with the need for eye drops, laser treatment, or glaucoma surgery
	+ Worse or lost vision
	+ Edema (swelling) in the back of your eye causing blurry vision
	+ Pigmentation: increased brown coloring of the iris (colored portion of the eye). This is permanent.
	+ Inflammation, which could make glaucoma or uveitis worse
* Risks from the injection
	+ Damage to the eyeball
	+ Infection that may occur days to weeks after the injection
	+ Bleeding in the eye
	+ Pain, irritation, or discomfort in the eye or surrounding tissues that may not go away
* Risks from the implant
	+ You could lose some cells from the inner layer of your cornea (the clear tissue at the front of your eye). If you lose many cells, you could lose vision.
	+ The implant could move to a different part of your eye. You might need surgery to move or remove the implant.

**By signing below, you consent (agree) that:**

* You read this informed consent form or had it read to you.
* You were told that you have glaucoma.
* Your questions about the DURYSTA implant have been answered.
* You consent to have the ophthalmologist place the DURYSTA implant in your \_\_\_\_\_\_\_\_\_\_\_ (“right,” “left”) eye.

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Patient Signature (or person authorized to sign for patient) Date

**[ADD TO LIST OF RISKS FOR RETREATMENT ONLY]**

Risks from multiple implants

* The Food and Drug Administration (FDA) recommends only one DURYSTA implant per eye.
* Multiple implants could increase the risk of losing cells from the cornea. This could lead to vision loss.
* Your ophthalmologist will talk to you about this risk if more than one implant is recommended.

**[ADD TO LAST SECTION FOR RETREATMENT ONLY]**

Your ophthalmologist recommends an additional implant. You understand that the FDA feels only one implant should be used. You may lose cells in your cornea, and have worse vision. The long-term risk of having another implant is unknown. You consent to have the ophthalmologist place another DURYTA in your \_\_\_\_\_\_\_\_\_\_\_\_\_ (“right,” “left”) eye.