Ophthalmology and Therapy

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ELEVATED INTRAOCULAR PRESSURE AFTER INTRAVITREAL STEROID INJECTION IN DIABETIC MACULAR OEDEMA: MONITORING AND MANAGEMENT

Goñi FJ, et al. Ophthalmol Ther.2016.

This slide deck represents the opinions of the authors. Sponsorship for this study was funded by Alimera Sciences Limited. For a full list of acknowledgments and disclosures for all authors of this article, please see the full text online. © The Author(s) 2016. Creative Commons Attribution Noncommercial License (CC BY-NC).

ALGORITHM FOR THE MONITORING AND MANAGEMENT OF IOP[1]

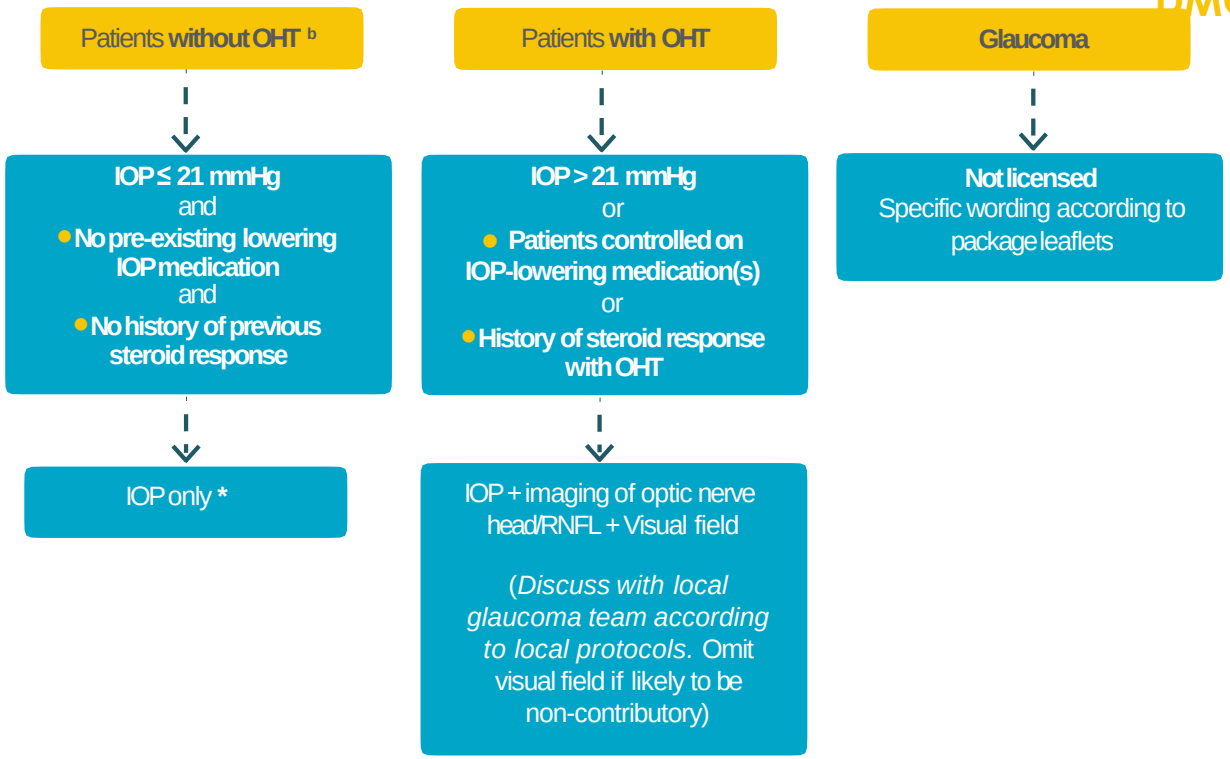
[a] Recommendations from a panel involving leading European glaucoma and retina specialists:

Francisco J. Goñi
Ingeborg Stalmans
Philippe Denis
Jean-Philippe Nordmann
Simon Taylor
Michael Diestelhorst
Antonio R. Figueiredo
David F. Garway-Heath

[b] Ocular hypertension as defined by the European Glaucoma Society guidelines

PRE-INJECTION CONSIDERATIONS[a]

for corticosteroid implants for the treatment of DMO

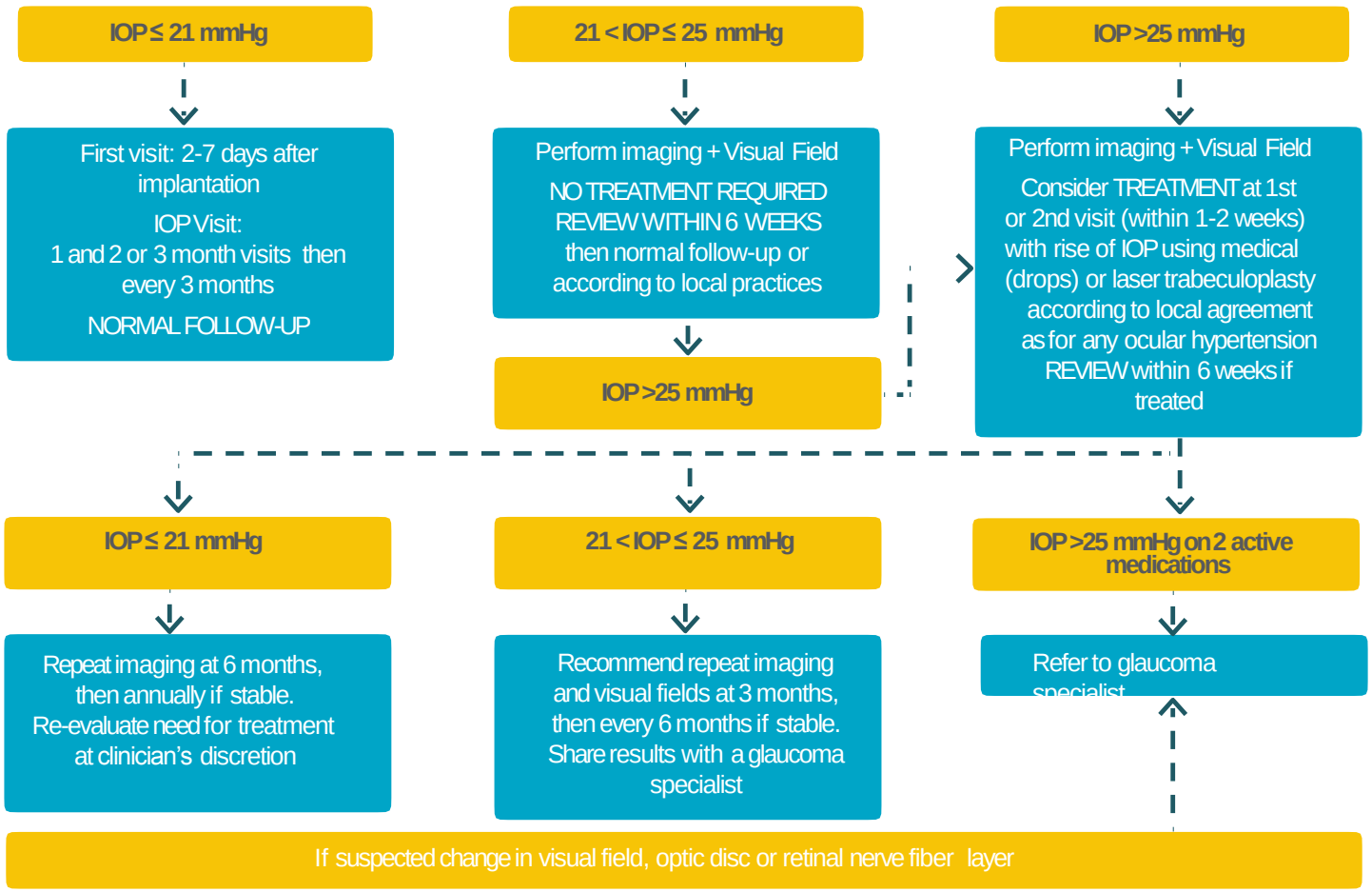


* if possible, combine imaging of optic nerve and fovea imaging to exclude normal-tension glaucoma

DMO- Diabetic Macular Oedema · IOP - Intraocular Pressure · OHT - Occular Hypertension · RNFL - Retinal nerve fibre layer

POST-INJECTION CONSIDERATIONS[a]

for corticosteroid implants for the treatment of DMO



Reference: 1. Goñi, FJ *et al.* Ophthalmology and Therapy 2016; 5(1): 47-61.

Prescribing Information UK ILUVIEN® 190 micrograms intravitreal implant in applicator. Refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** intravitreal implant in applicator. Each implant contains 190 micrograms of fluocinolone acetonide. Light brown coloured cylinder, approximately 3.5mm x 0.37mm in size. Implant applicator with 25 gauge needle. **Indication:** ILUVIEN is indicated for the treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. **Dosage and method of administration:** The recommended dose is one ILUVIEN implant in the affected eye. Administration in both eyes concurrently is not recommended. Each ILUVIEN implant releases fluocinolone acetonide for up to 36 months. An additional implant may be administered after 12 months if the patient experiences decreased vision or an increase in retinal thickness secondary to recurrent or worsening diabetic macular oedema. Retreatments should not be administered unless the potential benefits outweigh the risks. Only patients who have been insufficiently responsive to prior treatment with laser photocoagulation or other available therapies for diabetic macular oedema should be treated with ILUVIEN. **Children under 18:** No relevant use. **Special populations:** No dosage adjustments are necessary in elderly patients, or those with renal or hepatic impairment. **Method of Administration:** ILUVIEN should be administered by an ophthalmologist experienced in intravitreal injections. **Educational Guidance:** Prior to administering ILUVIEN, physicians should familiarise themselves with the ILUVIEN Administration Guide. **Contraindications:** the presence of pre-existing glaucoma or active or suspected ocular or periocular infection including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases. Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions:** Intravitreal injections have been associated with endophthalmitis, elevation in intraocular pressure, retinal detachments and vitreous haemorrhages or detachments. Patients should be instructed to report without delay any symptoms suggestive of endophthalmitis. Patient monitoring within two to seven days following the injection may permit early identification and treatment of ocular infection, increase in intraocular pressure or other complication. It is recommended that intraocular pressure be monitored at least quarterly thereafter. Use of intravitreal corticosteroids may cause cataracts, increased intraocular pressure, glaucoma and may increase the risk of secondary infections. The safety and efficacy of ILUVIEN administered to both eyes concurrently have not been studied. It is recommended that an implant is not administered to both eyes at the same visit. Concurrent treatment of both eyes is not recommended until the patient's systemic and ocular response to the first implant is known. There is a potential for implants to migrate into the anterior chamber, especially in patients with posterior capsular abnormalities, such as tears. This should be taken into consideration when examining patients complaining of visual disturbance after treatment. **Interactions:** No interaction studies with other medicinal products have been performed. **Pregnancy and lactation:** There are no adequate data from the use of intravitreal administered fluocinolone acetonide in pregnant women. As a precautionary measure it is preferable to avoid the use of ILUVIEN during pregnancy. Although systemic exposure of fluocinolone is very low, a risk benefit decision should be made prior to use of ILUVIEN during breast-feeding. **Driving and using machines:** ILUVIEN has minor influence on the ability to drive and use machines. Patients may experience temporarily reduced vision after administration of ILUVIEN and should refrain from driving or using machines until this has resolved. **Undesirable effects:** Very common (≥1/10): cataract operation, cataract, increased intraocular pressure; Common (≥1/100 to <1/10): glaucoma, trabeculectomy, eye pain, vitreous haemorrhage, conjunctival haemorrhage, blurred vision, glaucoma surgery, reduced visual acuity, vitrectomy, trabeculoplasty, vitreous floaters; Uncommon (≥1/1,000 to <1/100): endophthalmitis, headache, retinal vascular occlusion, optic nerve disorder, maculopathy, optic atrophy, conjunctival ulcer, iris neovascularisation, retinal exudates, vitreous degeneration, vitreous detachment, posterior capsule opacification, iris adhesions, ocular hyperaemia, sclera thinning, removal of extruded implant from sclera, eye discharge, eye pruritus, extrusion of implant, implant in line of sight, procedural complication, procedural pain, device dislocation. Consult the SmPC for full details of undesirable effects. **Overdose:** No case of overdose has been reported. **Legal classification:** POM. Pack size and NHS list price: £5,500.00 (ex VAT) for each ILUVIEN 190 micrograms intravitreal implant in applicator. **Marketing Authorisation number:** PL 41472/0001. **Marketing Authorisation Holder:** Alimera Sciences Limited, Royal Pavilion, Wellesley Road, Aldershot, Hampshire, GU11 1PZ, United Kingdom. **Date of preparation of PI:** October 2015

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For medical enquiries please email: medicalinformation@alimerasciences.com

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