Recommendations from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice, NICE MTA advice, (FAF3) unlicensed and off-label medicines and (FAF2) medicines not considered by SMC

11 – Eye

In alphabetical order

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL pre-filled syringe and pre-filled pen 07.11.16 *SMC Report No. 1209/16* NON SUBMISSION	NOT RECOMMENDED: adalimumab (Humira®) is not recommended for use within NHS Scotland for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of adalimumab in this indication. However, due to the significant time interval between product availability and the expected date of NICE guidance, not recommended advice has been issued.	NOT RECOMMENDED	
aflibercept 40mg/mL solution for intravitreal injection (Eylea®) *Bayer plc* 08.04.13 *SMC Report No 857/13* Patient Access Scheme	Accepted for use: aflibercept (Eylea®) is accepted for use within NHS Scotland in adults for the treatment of neovascular (wet) age-related macular degeneration. In two pivotal randomised controlled studies the non-inferiority of aflibercept versus monthly injections of another anti-VEGF treatment was demonstrated for the primary endpoint; proportion of patients who maintained vision at week 52. The economic analysis submitted by the company related to the use of aflibercept in patients with wet AMD who have not previously been treated with anti-VEGF therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Included on the Additional List, Specialist Use only for the indication in question.	October 2013
aflibercept, 40mg/mL solution for injection (Eylea®) *Bayer* 07.04.14 *SMC Report No 954/14* Patient Access Scheme	Accepted for use: aflibercept intravitreal (Eylea®) is accepted for use within NHS Scotland for adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion. Two randomised double-masked studies demonstrated that aflibercept improved best corrected visual acuity significantly more than sham injections in treatment-naïve adults with macular oedema secondary to central retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2014

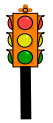
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
aflibercept, 40mg/mL solution for injection (Eylea®) *Bayer* 10.11.14 *SMC Report No 1003/14* Patient Access Scheme	Restricted use: aflibercept (Eylea®) is accepted for restricted use within NHS Scotland for adults for the treatment of visual impairment due to diabetic macular oedema (DMO). SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline. Intravitreal aflibercept significantly improved BCVA at 52 weeks compared with laser photocoagulation in two phase III, double-masked studies. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This advice is contingent upon the continuing availability of the patient access scheme, or a list price that is equivalent or lower, in NHS Scotland.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2014
aflibercept 40mg/mL solution for injection (Eylea®) *Bayer* 07.09.15 *SMC Report No 1074/15* Patient Access Scheme	Accepted: aflibercept (Eylea®) is accepted for use within NHS Scotland. Indication under review: for adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion. Aflibercept was associated with significant improvements over laser in visual acuity during a 6-month, randomized, double-masked phase III study in patients with branch retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. Aflibercept has previously been accepted by SMC for macular oedema secondary to central retinal vein occlusion. This advice now extends its use to patients with macular oedema secondary to branch retinal vein occlusion.	Included on the Additional list, Specialist use only.	November 2015
aflibercept 40mg/mL solution for injection (Eylea®) *Bayer plc* 10.10.16 *SMC Report No 1186/16* Patient Access Scheme	Accepted for use: aflibercept 40mg/mL solution for injection (Eylea®) is accepted for use within NHS Scotland for adults for the treatment of visual impairment due to myopic choroidal neovascularisation (myopic CNV). In a phase III, randomised, sham-controlled study in adults with myopic CNV, aflibercept was statistically superior to sham at improving visual acuity at 24 weeks. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Not included on the LJF, because clinicians do not support the formulary inclusion.	November 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bimatoprost (Lumigan®) *Allergan Ltd* 09.08.02 *SMC Report No. 07/02*	Accepted for use: bimatoprost (Lumigan®) is recommended for general use within the NHS in Scotland as adjunctive therapy to beta-blockers or as monotherapy in patients insufficiently responsive to, intolerant of or contraindicated to first-line therapy. Glaucoma & ocular hypertension. It should be used under the direction of an ophthalmologist.	Added to the Additional List.	February 2005
bimatoprost 0.03%, timolol 0.5% eye drops (Ganfort®) *Allergan Ltd* 09.10.06 *SMC Report No. 312/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: bimatoprost 0.03%, timolol 0.5% eye drops (Ganfort®) are accepted for use in NHS Scotland for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension, who are insufficiently responsive to topical beta-blockers or prostaglandin analogues and for whom this combination offers an appropriate choice.	'Not preferred' as suitable alternatives exist. Included in the prescribing notes	August 2008 April 2015
bimatoprost 0.3mg/mL single-dose eye drops (Lumigan UD®) *Allergan Ltd* 11.03.13 *SMC Report No. 839/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: bimatoprost 0.3mg/mL preservative-free eye drops (Lumigan UD®) are accepted for restricted use within NHS Scotland for reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers). SMC restriction: to use in patients who have proven sensitivity to the preservative benzalkonium chloride. SMC has previously accepted preserved bimatoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation with preservative.	Not included in the LJF because NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. The current LJF choice is travoprost.	March 2013
bimatoprost 0.3mg/mL plus timolol 5mg/mL, preservative-free, single-dose eye-drops (Ganfort® Unit Dose Preservative Free) *Allergan Ltd* 07.10.13 *SMC Report No. 906/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: bimatoprost plus timolol preservative-free eye-drops (Ganfort® Unit Dose Preservative Free) are accepted for restricted use within NHS Scotland for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. SMC restriction: to use in patients who have proven sensitivity to preservatives. SMC has previously accepted preserved bimatoprost plus timolol eye-drops for use in NHS Scotland. This preparation is more expensive than the equivalent multi-dose eye drop preparation with preservative.	Not included on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is travoprost or latanoprost preservative-free single dose eye drops for those with proven sensitivity to preservatives. Timolol is available as a preservative free preparation.	October 2013

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
brimonidine tartrate/timolol (Combigan®) eye drops *Allergan Ltd* 12.09.05 *SMC Report No. 196/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: brimonidine/timolol (Combigan®) eye drops are accepted for use in NHS Scotland for the reduction of intra-ocular pressure in patients, with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers alone and for whom brimonidine is an appropriate choice of adjuvant therapy. The combination product may be associated with a modest decrease in cost compared with the individual components and allows patients to administer fewer drops.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007
brinzolamide 10mg/mL eye drops (Azopt®) *Alcon Laboratories (UK) Limited* 14.04.09 *SMC Report No. 546/09* PRODUCT UPDATE (abbreviated submission)	Accpeted for use: brinzolamide (Azopt®) eye drops are accepted for use within NHS Scotland to decrease elevated intraocular pressure in ocular hypertension and open-angle glaucoma as monotherapy in patients unresponsive to beta-blockers or in patients in whom beta-blockers are contraindicated, or as adjunctive therapy to beta-blockers or prostaglandin analogues. This abbreviated submission relates to a licence extension to cover use of brinzolamide with prostaglandin analogues. For patients in whom brinzolamide is an appropriate choice of therapy, this licence extension is not associated with a price increase and is not expected to increase drug usage.	Added to the LJF as first choice.	July 2010
brinzolamide 10mg/mL and brimonidine tartrate 2mg/mL eye drops, suspension (Simbrinza®) *Alcon Eye Care UK Ltd* 10.11.14 *SMC Report No. 991/14* PRODUCT UPDATE (abbreviated submission)	Accepted for use: brinzolamide / brimonidine tartrate eye drops, suspension (Simbrinza®) is accepted for use within NHS Scotland for decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. There is no significant additional cost associated with the combination product compared with the individual components and it allows patients to administer fewer drops.	Included on the LJF as a prescribing note, for the indication in question.	November 2014
brinzolamide/timolol eye drops, suspension (Azarga®) *Alcon Laboratories (UK) Ltd* 07.09.09 *SMC Report No. 568/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: brinzolamide/timolol eye drops, suspension (Azarga®) are accepted for use within NHS Scotland for the decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. The combination product allows patients to administer fewer drops at a modestly increased cost over separate administration of the constituents.	Added to the LJF as a prescribing note.	July 2010
bromfenac (Yellox ®) 0.9 mg/mL eye drops solution *Bausch & Lomb* 10.10.11 SMC Report No. 740/11 NON SUBMISSION	NOT RECOMMENDED: bromfenac (Yellox ®) eye drops are not recommended for use within NHS Scotland treatment of postoperative ocular inflammation following cataract extraction in adults. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
carbomer 0.25% gel (Liquivisc®) *Allergan Ltd* 08.08.05 *SMC Report No. 191/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: carbomer 0.25% (Liquivisc®) gel is accepted for use in NHS Scotland for the symptomatic treatment of dry eye syndrome where a carbomer product is the treatment of choice. It differs in only minor respects from other carbomer products and is less expensive.	Formulary entry to be amended to include generic carbomers instead of the branded products.	August 2005
ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®) *Santen GmbH* 12.10.15 *SMC Report No. 1089/15*	Accepted: ciclosporin 1mg/mL (0.1%) eye drops emulsion (Ikervis®) is accepted for use within NHS Scotland. Indication under review: treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes. Ciclosporin eye drops, compared to vehicle, improved signs of corneal surface damage but not symptoms in patients with severe keratitis associated with dry eye disease.	Included on the Additional List, Specialist initiation, for the indication in question.	December 2015
dexamethasone 700 microgram intravitreal implant (Ozurdex®) *Allergan Ltd* 11.06.12 *SMC Report No. 652/10* 2nd RESUBMISSION	Restricted use: dexamethasone intravitreal implant (Ozurdex®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion. SMC restriction: for use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment. In two phase III studies dexamethasone 700 microgram intravitreal implant was superior to sham administration at day 90 for the proportion of patients with a best corrected visual acuity improvement ≥15 letters. Longer -term effectiveness of treatment is uncertain.	Included on the Additional List, Specialist Use only, for the treatment of patients with BRVO who are not suitable for laser therapy. Not included on the LJF, pending protocol, for the treatment of patients with CRVO.	August 2012
dexamethasone (Ozurdex®) 0.7 mg intravitreal implant *Allergan* 16.01.12 *SMC Report No. 751/11* NON SUBMISSION	NOT RECOMMENDED: dexamethasone (Ozurdex®) 0.7 mg intravitreal implant is not recommended for use within NHS Scotland for the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
dexamethasone 700 micrograms intravitreal implant in applicator (Ozurdex®) *Allergan Ltd.* 11.05.15 *SMC Report No. 1046/15*	Accepted for use: dexamethasone intravitreal implant (Ozurdex®) is accepted for use within NHS Scotland as treatment of adult patients with visual impairment due to diabetic macular oedema who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. Intravitreal dexamethasone improved visual acuity more than sham treatment in adult patients who were pseudophakic or had received prior treatment for diabetic macular oedema, based on subgroup analyses.	Included on the LJF as second choice, Specialist Use only, for the indication in question.	November 2016
dorzolamide 2% preservative-free unit dose eye drops (Trusopt®) *Merck Sharp & Dohme* 12.06.06 *SMC Report No. 238/06* PRODUCT UPDATE (abbreviated submission)	Restricted use: dorzolamide 2% preservative-free unit-dose eye drops (Trusopt®) are accepted for restricted use in NHS Scotland for the treatment of elevated intra-ocular pressure in ocular hypertension, open-angle glaucoma and pseudo-exfoliative glaucoma. They are licensed as adjunctive therapy to beta-blockers and as monotherapy in patients unresponsive to beta-blockers or in whom beta-blockers are contra-indicated. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation and should be restricted to use in patients for whom dorzolamide is appropriate and who have proven sensitivity to the preservative benzalkonium chloride.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007
dorzolamide 2% / timolol maleate 0.5% preservative-free unit dose eye drops (COSOPT®) *Merck Sharpe & Dohme* 11.12.06 *SMC Report No. 293/06* PRODUCT UPDATE (abbreviated submission)	Restricted use: dorzolamide / timolol preservative-free unit-dose eye drops (COSOPT®) are accepted for restricted use in NHS Scotland for the treatment of elevated intra-ocular pressure in patients with open-angle glaucoma and pseudo-exfoliative glaucoma when topical beta-blocker monotherapy is not sufficient. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation and should be restricted to use in patients for whom a combination of these two agents is appropriate and who have proven sensitivity to the preservative benzalkonium chloride.	Included on the Additional List, for Specialist Initiation, for the indication in question.	April 2014
epinastine (Relestat®) 0.5 mg/ml, eye drops, solution *Allergen Ltd* 08.05.06 *SMC Report No. 267/06* NON SUBMISSION	NOT RECOMMENDED: epinastine (Relestat®) is not recommended for use within NHSScotland for the treatment of the symptoms of seasonal allergic conjunctivitis. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
fluocinolone acetonide 190 micrograms intravitreal implant (Iluvien®) *Alimera Sciences Limited* 10.02.14 *SMC Report No. 864/13* RESUBMISSION Patient Access Scheme	Restricted use: fluocinolone acetonide intravitreal implant (Iluvien®) is accepted for restricted use within NHS Scotlandfor the treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies. SMC restriction: • only in patients in whom the affected eye is pseudophakic (has an artificial lens after cataract surgery) and; • retreatment would take place only if the patient had previously responded to treatment with fluocinolone acetonide and subsequently best corrected visual acuity had deteriorated to less than 20/32. The safety and efficacy of fluocinolone intravitreal implant was assessed in two randomised, double-masked, controlled phase III studies in patients with diabetic macular oedema. Significantly more patients treated with fluocinolone acetonide had a clinically meaningful improvement in visual acuity at two and three years versus sham injection. Subgroup analyses supported this finding in patients with chronic diabetic macular oedema (median duration at least three years) and in patients who were pseudophakic at baseline. Raised intraocular pressure is an important safety issue. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fluocinolone. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, for Specialist Use only, for the indication in question.	May 2014
fluorescein (Anatera®) 10% injection	Fluorescein angiography of the ocular fundus.	Included on the LJF as a first choice, for the indication in question.	July 2016
idebenone (Daruma®) *Wyeth Pharmaceuticals*	Mitochondrial cytopathies 	Added to the Additional List. The unlicensed use of idebenone for the treatment of mitochondrial cytopathies has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - Specialist use only.	January 2006
idebenone (Raxone®) 150mg film-coated tablets *Santhera Pharmaceuticals UK Ltd* 08.05.17 *SMC Report No. 1226/17* Patient Access Scheme	Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON). SMC restriction: to patients with LHON who are not yet blind i.e. they do not meet the UK criteria to be registered as severely sight impaired.	Not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 9th November 2017.	July 2017

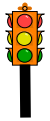
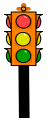
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ketotifen hydrogen fumarate (Zaditen® Eye Drops) *Novartis* 10.11.03 *SMC Report No. 65/03* NON SUBMISSION	NOT RECOMMENDED: In the absence of a submission to SMC from the licence holder, ketotifen hydrogen fumarate (Zaditen® Eye Drops) is not recommended for use within NHS Scotland for the symptomatic treatment of seasonal allergic conjunctivitis.	NOT RECOMMENDED	
latanoprost (Xalatan®) *Pfizer* 12.07.04 *SMC Report No. 102/04*	Restricted use: latanoprost (Xalatan®) is accepted for restricted use within NHS Scotland for the treatment of raised intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma. Use of latanoprost, as monotherapy, should be restricted to patients who have contraindications to beta-blockers or have a history of adverse reactions to this group of drugs. It may also be indicated in addition to beta-blockers when required. It is one of a number of topical ocular prostaglandin analogue preparations licensed in the UK for this indication. In reducing IOP it is comparable in effect to other drugs in its class.	Added to the Formulary.	
latanoprost, timolol eyedrops (Xalacom®) *Pfizer Ltd* 14.01.08 *SMC Report No. 432/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: latanoprost, timolol (Xalacom®) is accepted for use within NHS Scotland for reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. This abbreviated submission relates to a licence extension to cover use of this medicine in patients insufficiently responsive to a prostaglandin analogue used alone. Xalacom® is suitable for patients in whom timolol and latanoprost are appropriate choices of beta-blocker and prostaglandin analogue respectively. It costs less than the individual preparations.	Added to the Additional List	August 2008
latanoprost 50microgram/mL preservative-free single-dose eye-drops (Monopost®) *Spectrum Thea Pharmaceuticals Ltd* 08.07.13 *SMC Report No. 879/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: latanoprost preservative-free eye-drops (Monopost®) are accepted for restricted use within NHS Scotland for the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension. SMC restriction: to use in patients who have proven sensitivity to the preservative benzalkonium chloride. SMC has previously accepted preserved latanoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent generic multi-dose eye drop preparation with preservative.	Included on the LJF as a prescribing note, Specialist initiation, for the indication in question.	July 2013
loteprednol etabonate 0.5% 5mg/ml (Lotemax 0.5% eye drops, suspension) *Bausch & Lomb GmbH* 09.06.08 *SMC Report No. 484/08* NON SUBMISSION	NOT RECOMMENDED: loteprednol etabonate 5mg/ml eye drops (Lotemax 0.5% eye drops, suspension) are not recommended for the treatment of post-operative inflammation following ocular surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
nepafenac (Nevanac ®) *Alcon Laboratories* 09.11.09 *SMC Report No. 588/09* NON SUBMISSION	NOT RECOMMENDED: in the absence of a submission from the holder of the marketing authorisation. nepafenac (Nevanac®) is not recommended for use within NHSScotland for prevention and treatment of postoperative pain and inflammation associated with cataract surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
nepafenac 1mg/mL eye drops, suspension (Nevanac®) *Alcon Laboratories (UK) Ltd* 12.11.12 *SMC Report No. 813/12*	Accepted for use: nepafenac (Nevanac®) is accepted for use within NHS Scotland for reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. In the pivotal study which included diabetic patients who had undergone cataract surgery, nepafenac eye drops significantly reduced the incidence of macular oedema compared to vehicle.	Included on the LJF as a prescribing note, for Specialist Initiation only, for the indication in question.	May 2014
nepafenac 3mg/mL eye drops, suspension (Nevanac®) *Alcon Eye Care Ltd* 11.05.17 *SMC Report No. 1228/17* PRODUCT UPDATE (abbreviated submission)	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017
ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection (Jetrea®) *ThromboGenics NV* 11.08.14 *SMC Report No. 892/13* RESUBMISSION	Restricted use: ocriplasmin (Jetrea®) is accepted for restricted use within NHS Scotland in adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. SMC restriction: patients with vitreomacular traction plus macular hole, regardless of whether they have epiretinal membrane formation, and in patients with vitreomacular traction alone (no epiretinal membrane and no macular hole). In two randomised, controlled double-masked studies, significantly more patients treated with ocriplasmin than placebo achieved resolution of vitreomacular adhesions which may correlate with improved visual acuity.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	October 2014
olopatadine 1mg/ml eye drops, solution (Opatanol®) *Alcon Laboratories (UK) Ltd* 09.01.06 *SMC Report No. 59/03* RESUBMISSION	Accepted for use: olopatadine eye drops (Opatanol®) are accepted for use within NHS Scotland for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis. Olopatadine is a new, locally applied antihistamine and anti-allergen. It appears to have similar efficacy to other ocular preparations for seasonal allergic conjunctivitis and a lower price than some competitors, suggesting that it is cost effective compared to these higher-priced products.	Added to the Additional List.	March 2007

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
pegaptanib 0.3mg, solution for intravitreal injection (Macugen®) *Pfizer Ltd* 07.08.06 *SMC Report No. 290/06*	Restricted use: pegaptanib for intravitreal injection (Macugen®) is accepted for restricted use within NHS Scotland for the treatment of neovascular (wet) age-related macular degeneration (AMD). It has been shown to reduce the rate of loss of visual acuity in patients with subfoveal neovascular AMD. Pegaptanib should be restricted to patients with visual acuity between 6/12 to 6/60 (inclusive) and should be stopped if visual acuity falls below 6/60 during treatment or where severe visual loss is experienced. The cost effectiveness of pegaptanib in patients who are also receiving photodynamic therapy has, however, not been demonstrated.	Added to the Additional List, for Specialist Use only. Advice superseded by NICE MTA 155 - there are difference in the advice.	October 2006
ranibizumab 10mg/ml solution for intravitreal injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* 11.06.07 *SMC Report No. 381/07*	Accepted for use: ranibizumab (Lucentis®) is accepted for use within NHS Scotland for the treatment of neovascular (wet) age-related macular degeneration (AMD). Ranibizumab reduces the rate of visual acuity loss and increases visual acuity. It should be stopped if visual acuity falls persistently below 6/60 during treatment.	Added to the Additional List, for Specialist Use only. SMC advice superseded by NICE MTA 155 – no change to recommendation. Prefilled syringes are now available, they are approved for use as above. Please note Aflibercept (Eylea®) should be used in preference of ranibizumab.	July 2007 October 2013
ranibizumab, 10mg/mL solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* 10.12.12 *SMC Report No. 711/11* RESUBMISSION Patient Access Scheme	Restricted use: ranibizumab (Lucentis®) is accepted for restricted use within NHS Scotland for the treatment of visual impairment due to diabetic macular oedema (DMO) in adults. SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline. Ranibizumab significantly improved visual acuity over 12 months compared with standard laser photocoagulation treatment. Open label extension results up to 3 years suggest maintenance of effect. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	Included on the Additional List, Specialist Use only, for the indication in question. Prefilled syringes are now available, they are approved for use as above. Please note Aflibercept (Eylea®) should be used in preference of ranibizumab.	January 2013 December 2014

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ranibizumab, 10mg/mL solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* 07.11.11 *SMC Report No. 732/11* Patient Access Scheme	Restricted use: ranibizumab (Lucentis®) is accepted for restricted use within NHS Scotland for the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. SMC restriction: restricted to use in patients with macular oedema secondary to central retinal vein occlusion (CRVO). Ranibizumab was associated with significant improvements in visual acuity during 6-month sham-controlled treatment in one study in patients with branch retinal vein occlusion and in one study in patients with central retinal vein occlusion. The benefits were considerable in patients with CRVO and there is a lack of alternative treatment options for these patients. The submitting company did not present a sufficiently robust economic analysis for ranibizumab in the treatment of BRVO to gain acceptance by SMC.	Added to the Additional List, for Specialist Use only, for CRVO. Prefilled syringes are now available, they are approved for use as above. Please note Aflibercept (Eylea®) should be used in preference of ranibizumab.	December 2011 April 2014
ranibizumab, 10mg/mL solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* 13.05.13 *SMC Report No. 732/11* RESUBMISSION Patient Access Scheme	Accepted for use: ranibizumab (Lucentis®) is accepted for use within NHS Scotland for the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. This resubmission relates to branch RVO only. Ranibizumab was associated with significant improvements in visual acuity during 6-month sham-controlled treatment in a phase III randomised double-blind study in patients with branch retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. SMC has previously accepted ranibizumab for use in macular oedema secondary to central retinal vein occlusion (CRVO). This advice now extends its use to patients with branch retinal vein occlusion (BRVO).	Included on the Additional List, Specialist Us only, for the indication in question. See also entry above Prefilled syringes are now available, they are approved for use as above.	July 2013

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ranibizumab, 10mg/mL, solution for injection (Lucentis®) *Novartis Pharmaceuticals UK Ltd* 11.11.13 *SMC Report No. 907/13* Patient Access Scheme	Accepted for use: ranibizumab (Lucentis®) is accepted for use within NHS Scotland as treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults. In patients with choroidal neovascularisation secondary to pathologic myopia, ranibizumab intravitreal injection was associated with a significant improvement in visual acuity of 8.4 Early Treatment Diabetic Retinopathy Study letters at three months compared with photodynamic therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. June 2017 - licence has been extended to cover the treatment of visual impairment due to choroidal neovascularisation associated with causes other than neovascular (wet) age-related macular degeneration or pathologic myopia.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. Prefilled syringes are now available. Please refer to SMC no. 907/13 in communication with the ophtlalmology physicians and pharmacists.	December 2013
riboflavin (isotonic or hypotonic) eye drops *Veni Vidi*	Treatment of keratoconus	Added to the Additional List, for Specialist Use only	January 2011
sodium chloride 5% preservative-free eye drops (PF DROPS™ Sodium Chloride 5% eye drops) *Moorfields Pharmaceuticals*	Treatment of corneal oedema	Included in the LJF as a first choice preparation for the indication in question See also medical devices table	January 2015
sodium hyaluronate 1.2% (OVD®) *Beaver-Visitec International Ltd*	Ophthalmic cataract surgery	Added to the Additional List, for Specialist Use only.	December 2010
tafluprost 15 micrograms/ml preservative-free eye drops single-dose container (Saflutan®) *Merck Sharpe & Dohme Ltd* 07.12.09 *SMC Report No: 581/09*	Restricted Use: tafluprost preservative-free eye drops (Saflutan®) are accepted for restricted use within NHS Scotland for the reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension - as monotherapy: in patients who would benefit from preservative-free eye-drops, who are insufficiently responsive to first-line therapy, or who are intolerant or contraindicated to first-line therapy - or as adjunctive therapy to beta-blockers. Tafluprost is restricted to use in patients who cannot tolerate currently available prostaglandin preparations due to proven sensitivity to the preservative benzalkonium chloride. Preservative-free tafluprost has shown equivalence to a formulation of tafluprost with preservative in lowering intraocular pressure. The adverse event profile was similar for both formulations. The formulation of tafluprost with preservative has shown non-inferiority to a beta-blocker but failed to demonstrate non-inferiority to a prostaglandin comparator in a pre-specified primary analysis. Saflutan is the only preservative-free prostaglandin eye drop available.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
tafluprost 15micrograms/mL and timolol 5mg/mL preservative-free eye drops (Taptiqom®) *Santen GmbH* 07.09.15 *SMC Report No. 1085/15* PRODUCT UPDATE (abbreviated submission)	Restricted: tafluprost 15 micrograms/mL and timolol 5mg/mL preservative-free eye drops (Taptiqom®) are accepted for restricted use within NHS Scotland. Indication under review: Reduction of intraocular pressure in adult patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues and require a combination therapy, and who would benefit from preservative-free eye drops. SMC restriction: to use in patients who have proven sensitivity to preservatives. The combination product costs less than preservative-free tafluprost and timolol eye drops administered separately.	Not included on the LJF because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question.	September 2015
timolol, 1mg/g eye gel for single-dose container (Tiopex®) *Spectrum Thea Pharmaceuticals Limited* 10.02.14 *SMC Report No. 941/14* PRODUCT UPDATE (abbreviated submission)	Restricted use: timolol gel eye drops (Tiopex®) are accepted for restricted use within NHS Scotland for reduction of the elevated intraocular pressure in patients with: - ocular hypertension, - chronic open angle glaucoma. SMC restriction: to use in patients who have proven sensitivity to preservatives. The cost of this once daily preservative-free formulation is significantly cheaper than the twice daily preservative-free preparation and may for some patients offer advantages in the lower concentration and reduced applications. Preserved timolol eye drops are included in the drug tariff and are significantly cheaper than preservative-free preparations.	Included on the LJF as a prescribing note, for the indication in question.	February 2014
Tisseel Kit (fibrin sealant) *Baxter*	Opthalmic surgery involving the conjunctiva and cornea 	Added to the Additional List, for Specialist Use only. Tisseel Kit for ophthalmic surgery involving the conjunctiva and cornea has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. Product discontinued	September 2009 December 2015
Tisseel RTU (ready to use) fibrin glue	Opthalmic surgery involving the conjunctiva and cornea as tissue adhesive. 	Included on the Additional List, for Specialist Use only. Classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	August 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
travoprost (Travatan®) *Alcon Laboratories* 09.02.04 *SMC Report No. 60/04*	Restricted use: travoprost (Travatan®) is accepted for restricted use within NHS Scotland for the treatment of raised intraocular pressure (IOP) in patients with ocular hypertension or open-angle glaucoma. Use of travoprost, as monotherapy, should be restricted to patients who have contraindications to beta-blockers or have a history of adverse reactions to this group of drugs. It may also be indicated in addition to beta-blockers when required. It is one of a number of topical ocular prostaglandin analogue preparations licensed in the UK for this indication. In reducing IOP it is comparable in effect to other drugs in its class.	Added to the Additional List. First choice prostaglandin analogue in LJF	April 2004 July 2010
travoprost 0.004% / timolol 0.5% eye drops (Duotrav®) *Alcon Laboratories (UK) Ltd* 07.08.06 *SMC Report No. 294/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: travoprost/timolol (Duotrav®) eye drops are accepted for use in NHS Scotland for whom this is an appropriate combination of agents. They decrease intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues alone. There is no significant additional cost associated with the combination product compared with the individual components and it allows patients to administer fewer drops.	Added to the LJF as a prescribing note Removed from prescribing notes	July 2010 April 2015
travoprost 40 micrograms/mL eye drops (Travatan®) *Alcon Eye Care UK Ltd* 12.10.15 *SMC Report No. 1091/15* PRODUCT UPDATE (abbreviated submission)	Accepted: travoprost (Travatan®) is accepted for use within NHS Scotland. Indication under review: decrease of elevated intraocular pressure in paediatric patients aged 2 months to <18 years with ocular hypertension or paediatric glaucoma. In a randomised, double-masked study of paediatric patients with glaucoma or ocular hypertension, travoprost was demonstrated to be non-inferior to a beta blocker eye drop preparation in terms of mean reduction in intra-ocular pressure. Another topical ocular prostaglandin analogue preparation is licensed for use in children for this indication and is considerably cheaper. In reducing intra-ocular pressure, travoprost is comparable in effect to other drugs in its class.	Included on the LJF for the indication in question.	October 2015
Xailin Night Eye ointment (white soft paraffin 57.3%, white mineral oil 42.5%, lanolin alcohols 0.2%)	Lubrication of dry eyes.	Included on the LJF.	November 2015