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

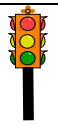
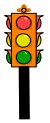
7 – Obstetrics, Gynaecology and Urinary-tract disorders

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**
alprostadil topical cream (Vitaros®) *Takeda Ltd.*	Erectile dysfunction	Included on the LJF as a 2nd choice, Specialist initiation.	July 2015
avanafil (Spedra®) 50mg, 100mg and 200mg tablets *A Menarini Farmaceutica Internazionale SRL* 07.09.15 *SMC Report No. 980/14*	NOT RECOMMENDED: avanafil (Spedra®) is not recommended for use within NHS Scotland. Indication under review: Treatment of erectile dysfunction (ED) in adult men. In order for avanafil to be effective, sexual stimulation is required. The pivotal studies demonstrated a statistically significant improvement in ED after administration of avanafil compared with placebo in the general ED population and in patients with ED due to diabetes or following radical prostatectomy. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
botulinum Toxin – A (Botox®) *Allergan*	Use for intractable detrusor over activity 	It was agreed that botulinum should be added to the Additional List. Botulinum use for intractable overactive bladder has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	July 2008 Superseded by SMC advice 916/13
botulinum Toxin – A (Dysport®) *Ipsen*	Use for severe overactive bladder with urge incontinence, with urodynamically proven detrusor activity 	It was agreed that botulinum should be added to the Additional List. Botulinum use for severe overactive bladder has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	October 2008 Decision superseded by SMC advice 931/13

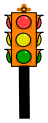
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
botulinum toxin type A 50, 100, 200 Allergan units/vial (Botox®) *Allergan Ltd* 07.10.13 *SMC Report No. 916/13*	Accepted for use: botulinum toxin type A (Botox®) is accepted for use within NHS Scotland for management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required. In two phase III, double-blind, placebo-controlled studies, in which all patients received best supportive care, botulinum toxin type A 200 units (licensed dose) was significantly superior to placebo for mean reduction in weekly urinary incontinence episodes, from baseline to week six. There are currently limited data on re-treatment.	Not included on the LJF, pending protocol. Not included on the LJF, because clinicians do not support the formulary inclusion	October 2013 May 2016
botulinum toxin type A powder for solution for injection (BOTOX®) *Allergan Ltd* 07.07.14 *SMC Report No. 931/13*	Restricted use: botulinum toxin type A (BOTOX®) is accepted for restricted use within NHS Scotland for the management of bladder dysfunctions in adult patients who are not adequately managed with anticholinergics: overactive bladder with symptoms of urinary incontinence, urgency and frequency. SMC restriction: Patients who have failed appropriate oral treatment options. In two phase III double-blind studies, botulinum toxin type A (BOTOX®) significantly reduced the mean daily number of urinary incontinence episodes compared with placebo.	Included on the Additional List, Specialist Use only, for the indication in question.	May 2016
cabergoline (Dostinex®) *Pharmacia*	As suppression of initiaition of lactation in women over 24 weeks with a foetal loss.	Added to the LJF as a prescribing note, for Specialist Use only.	December 2012
carbetocin (Pabal®) 100micrograms/1mL solution for injection *Ferring Pharmaceuticals Ltd* 07.08.06 *SMC Report No. 309/06* NON SUBMISSION	NOT RECOMMENDED: carbetocin (Pabal®) 100micrograms/1mL solution for injection, is not recommended for use within NHSScotland for the prevention of uterine atony and excessive bleeding following delivery of the infant by Caesarean section under epidural or spinal anaesthesia. 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	
choriogonadotropin alfa (Ovitrelle®) 250micrograms/0.5mL pre filled syringe *Serono Ltd* 09.10.06 *SMC Report No. 263/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: choriogonadotropin alfa 250micrograms/0.5mL pre-filled syringe (Ovitrelle®) is accepted for use in NHS Scotland for use in women undergoing superovulation prior to assisted reproduction techniques such as in vitro fertilisation, where the use of this preparation is appropriate. Unlike the vial formulation available previously it does not require reconstitution, and the cost per dose is the same. This replaces advice previously issued by the Scottish Medicines Consortium for Ovitrelle in May 2006 following a non-submission.	New formulation of a drug already included in the Formulary.	October 2007

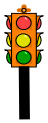
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
choriogonadotropin alfa (Ovitrelle®) 250micrograms/0.5mL pre filled syringe *Serono Ltd* 09.10.06 *SMC Report No. 264/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: choriogonadotropin alfa 250micrograms/0.5mL pre-filled syringe (Ovitrelle®) is accepted for use in NHS Scotland for the treatment of anovulatory or oligo-ovulatory women, where the use of this preparation is appropriate. Unlike the vial formulation available previously it does not require reconstitution, and the cost per dose is the same. This replaces advice previously issued by the Scottish Medicines Consortium for Ovitrelle in May 2006 following a non-submission.	New formulation of a drug already included in the Formulary.	October 2007
copper Wire IUD (surface area 380mm2) (TT380)	Contraception (long-term)	Added to the Formulary as first choice copper IUD.	May 2006
corifollitropin alfa (Elonva®) 100 and 150mcg solution for injection *MSD* 13.07.10 SMC Report No. 633/10 NON SUBMISSION	NOT RECOMMENDED: corifollitropin alfa (Elonva®) is not recommended for use within NHSScotland for the treatment of Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program. 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	
dapoxetine hydrochloride 30mg and 60 mg film-coated tablets (Priligy®) *A Menarini Farmaceutica Internazionale SRL* 07.07.14 *SMC Report No. 987/14* NON SUBMISSION	NOT RECOMMENDED: dapoxetine hydrochloride (Priligy®) is not recommended for use within NHS Scotland for the treatment of premature ejaculation (PE) in adult men aged 18 to 64 years. 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	
darifenacin 7.5mg, 15mg prolonged-release tablets (Emselex®) *Ardana Bioscience* 11.06.07 *SMC Report No. 377/07*	Restricted use: darifenacin (Emselex®) is accepted for restricted use within NHS Scotland for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Darifenacin is effective in reducing symptoms associated with overactive bladder, including frequency, urgency and incontinence and the treatment effect is similar to another antimuscarinic. Darifenacin is associated with adverse effects typical of antimuscarinic agents used in this condition. It is restricted to second line use as there are cheaper antimuscarinics available that would normally be used as first-line agents.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	June 2008

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**
desmopressin 25 microgram, 50 microgram oral lyophilisate (Noqdirna®) *Ferring Pharmaceuticals Ltd* 07.08.17 *SMC Report No. 1218/17* RESUBMISSION	Symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. SMC restriction: For use in patients aged 65 years and over.	Formulary classification not yet decided – waiting for information from clinicans.	
desogestrel (Cerazette®) *Organon Laboratories* 08.09.03 *SMC Report No. 36/03* RESUBMISSION	Restricted use: desogestrel is now available as a progestogen-only contraceptive pill (POP), which has been shown to inhibit ovulation to a substantially greater extent than other POPs. Its use should be restricted to those individuals who cannot tolerate oestrogen containing contraceptives or in whom those preparations are contraindicated.	Approved for use - added to the Additional List. Cerazette® is a new POP and has been shown to inhibit ovulation more than other POPs but is more expensive. The first choice POPs in the Formulary are Micronor® and Noriday®.	November 2003
desogestrel (Cerazette®, generic brands (Aizea®, Cerelle®, Nacrez®, Zelleta®)	Contraception in the immediate postnatal period. 	Included on the Additional List as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	July 2015
dinoprostone 10mg vaginal delivery system (Propess®) *Ferring Pharmaceuticals Ltd* 10.07.06 *SMC Report No. 283/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: dinoprostone 10mg vaginal delivery system (Propess®) is accepted for use in NHS Scotland for initiation of cervical ripening in patients at term (from 38th week of gestation). This formulation replaces a product which released 5mg over 12 hours from a different 10mg vaginal delivery system. The new pessary formulation can remain in place for up to 24 hours where necessary and the cost per pessary is unchanged.	'Not preferred' in Lothian for initiation of cervical ripening in patients at term (from 38th week of gestation).	September 2006
dinoprostone pessaries (Propess®) *Ferring*	Outpatient Induction of labour 	Added to the Additional List, for Specialist Use only. Dinoprostone for outpatient induction of labour has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	September 2009
domperidone	Augmentation of lactation. 	Added to the Formulary. General use with restrictions. Domperidone (Motilium®) has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2012

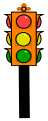
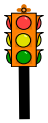
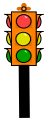
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
duloxetine (Yentreve®) *Eli Lilly and Company* 11.10.04 SMC Report No. 119/04	Restricted use: duloxetine is accepted for restricted use within NHS Scotland for the treatment of moderate to severe stress urinary incontinence (SUI). It should be used only as part of an overall management strategy for SUI in addition to pelvic floor muscle training. Patients should be reviewed after 12 weeks of therapy to assess progress and determine whether it is appropriate to continue treatment. Because of the short duration of treatment in the studies supplied, it is recommended that the manufacturers collect further data on the long-term effects of this pharmacological approach to the management of SUI.	Added to the LJF as second choice treatment for moderate to severe stress incontinence. First choice treatment is pelvic floor muscle exercises. Until such time as further evidence is available on safety, efficacy and cost effectiveness, the prescribing of duloxetine should only be initiated in secondary care.	May 2005
dutasteride (Avodart®) *GlaxoSmithKline* 09.05.03 *SMC Report No. 37/03*	Accepted for use: dutasteride has demonstrated similar efficacy and safety to alternative 5a-reductase inhibitors in reducing prostate volume in patients with BPH. Dutasteride is likely to be cost-neutral to NHS Scotland in the treatment of BPH.	Added to the Additional List	January 2004 and January 2006
dutasteride (Avodart®) *GlaxoSmithKline*	Lower urinary tract symptoms due to BPH	To remain on the Additional List.	January 2006
dutasteride 0.5mg plus tamsulosin 0.4mg capsule (Combodart®) *GlaxoSmithKline* 09.08.10 *SMC Report No 628/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: dutasteride plus tamsulosin (Combodart®) is accepted for use within NHS Scotland. Indications under review: Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH); Reduction in the risk of acute urinary retention and surgery in patients with moderate to severe symptoms of BPH. In patients for whom concomitant use of these medicines is appropriate, this combination allows administration of a single capsule at reduced cost compared to the individual components	Added to the Additional List when the combination of these medicines is deemed appropriate.	August 2010
estradiol / dienogest (Qlaira®) *Bayer Schering Pharma* 12.10.09 *SMC Report No. 583/09* NON SUBMISSION	NOT RECOMMENDED: estradiol/dienogest (Qlaira®) is not recommended for use within NHSScotland for oral contraception. 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	
ethinylestradiol 30micrograms and drospirenone 3mg (Yasmin®) *Bayer Schering Pharma* 07.02.03 *SMC Report No. 23/03* *RESUBMISSION*	NOT RECOMMENDED: drospirenone/ethinylestradiol (Yasmin®) is not recommended for use within NHS Scotland. Indication under review: oral contraception. Drospirenone/ethinylestradiol has been shown to have similar contraceptive effectiveness to other combined oral contraceptives in routine use, with no significant differences in adverse event profile. The manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	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**
ethinylestradiol 30microgram and levonorgestrel 150microgram (Rigevidon® 30/150 microgram) film-coated tablets *Consilient Health Limited* 11.10.10 *SMC Report No. 646/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ethinylestradiol 30microgram/levonorgestrel 150microgram (Rigevidon®): is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom ethinylestradiol/levonorgestrel is an appropriate contraceptive, Rigevidon® provides an alternative to existing preparations at a lower cost.	Added to the LJF as first choice.	March 2011
ethinylestradiol 20 microgram / gestodene 75microgram (Millinette® 20/75microgram) film-coated tablets ethinylestradiol 30 microgram / gestodene 75microgram (Millinette® 30/75microgram) film-coated tablets *Consilient Health Limited* 11.10.10 *SMC Report No. 644/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ethinylestradiol 20microgram/gestodene 75microgram and ethinylestradiol 30microgram/gestodene 75microgram (Millinette®): is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom ethinylestradiol /gestodene is an appropriate contraceptive, Millinette® provides an alternative to existing preparations at lower cost.	Millinette® 30/75 added to the LJF as second choice. Millinette® 20/75 'Not preferred' in Lothian as suitable alternatives exist.	March 2011
ethinylestradiol 20microgram / desogestrel 150microgram (Gedarel® 20/150 microgram) film-coated tablets ethinylestradiol 30microgram / desogestrel 150microgram (Gedarel® 30/150 microgram) film-coated tablets *Consilient Health Limited* 11.10.10 *SMC Report No. 643/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ethinylestradiol 20microgram/desogestrel 150microgram and ethinylestradiol 30microgram/desogestrel 150microgram (Gedarel®) is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom ethinylestradiol /desogestrel is an appropriate contraceptive, Gedarel® provides an alternative to existing preparations at lower cost.	Gedarel® 30/150 added to the LJF as second choice Gedarel® 20/150 'Not preferred' in Lothian as suitable alternatives exist.	March 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**
ethinylestradiol 30/40microgram/levonorgestrel 50/75/125microgram (TriRegol®) *Consilient Health Limited* 11.10.10 *SMC Report No. 645/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ethinylestradiol 30/40 plus levonorgestrel 50/75/125 microgram (TriRegol®): is accepted for use within NHS Scotland. Indication under review: oral contraception. For patients in whom phasic ethinylestradiol and levonorgestrel is an appropriate contraceptive, TriRegol® provides an alternative to the existing preparation at lower cost.	'Not preferred' in Lothian as suitable alternatives exist.	March 2011
11.7mg etonogestrel / 2.7mg ethinylestradiol vaginal ring (NuvaRing®) *Schering-Plough* 12.10.09 *SMC Report No. 502/08* RESUBMISSION	Accepted for use: etonogestrel / ethinylestradiol vaginal ring (NuvaRing®) is accepted for use within NHS Scotland for contraception. Results from two randomised phase III clinical studies indicate that the contraceptive efficacy of NuvaRing® is similar to that of two combined oral contraceptives. NuvaRing® produces good cycle control and user acceptability. Cost-effectiveness has been demonstrated in women who chose to discontinue oral contraceptives. Other non-oral contraceptives are available at lower cost.	Added to the Additional List.	March 2010
etonogestrel implant 68mg (Nexplanon®) *Merck Sharp & Dohme Limited* 13.12.10 *SMC Report No. 655/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: etonogestrel implant 68mg (Nexplanon®) is accepted for use within NHS Scotland. Indication under review: contraception. In patients for whom a long-acting etonogestrel implant is an appropriate choice of contraception. This formulation of etonogestrel implant is X-ray opaque, allowing verification of presence and location of implant.	Added to the Formulary. LJF section to be amended to reflect the change in name from Implanon to Nexplanon.	December 2010
etonogestrel (Nexplanon®) *Organon (MSD)*	Contraception within 72 hours postpartum 	Added to the Additional List, for Specialist Use only. Etonogestrel has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2012
fenticonazole 2% vaginal cream and 200mg/600mg vaginal capsules (Ginoxin®) *Recordati Pharmaceuticals Limited* 07.02.11 *SMC Report No 691/11* NON SUBMISSION	NOT RECOMMENDED: fenticonazole (Ginoxin®) is not recommended for use within NHS Scotland. Indication under review: treatment of vulvovaginal candidiasis. 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**
fesoterodine fumarate 4mg and 8mg prolonged release tablets (Toviaz®) *Pfizer Ltd* 07.07.08 *SMC Report No 480/08*	Restricted use: fesoterodine fumarate prolonged release tablets (Toviaz®) is accepted for restricted use within NHS Scotland for treatment of the symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur in patients with overactive bladder syndrome. Fesoterodine is effective in reducing symptoms associated with overactive bladder syndrome without a neurological cause and was of equivalent efficacy to a comparator antimuscarinic agent in one study. Fesoterodine is associated with adverse effects typical of antimuscarinic agents used in this condition. It is restricted to second-line use as there are cheaper antimuscarinics available that would normally be used as first-line agents.	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.	December 2012
fluconazole (oral) (Diflucan®) *Pfizer*	Empirical treatment of breast pain (mastalgia) during breastfeeding. 	Not preferred in Lothian. Fluconazole (Diflucan®) has been categorised **BLACK** under the ADTC 'Policy for the use of unlicensed (and off label use) Medicines in NHS Lothian, for the treatment of mastalgia.	July 2007
follitropin alfa 75 units, 150 units, 225 units, 300 units, 450 units pre-filled pen for subcutaneous injection (Bemfola®) *FINOX Biotech* 09.02.15 *SMC Report No. 1025/15*	Accepted for use: follitropin alfa (Bemfola®) is accepted for use within NHS Scotland in adult women for: • anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer. • in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and follicle-stimulating hormone (FSH) deficiency. In clinical trials these patients were defined by an endogenous serum LH level <1.2 units/L. In adult men for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human chorionic gonadotrophin (hCG) therapy. Follitropin alfa (Bemfola®) is a biosimilar that has demonstrated clinical equivalence to another follitropin alfa product for stimulation of multi-follicular development for superovulation in ART. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	Included on the LJF as a first choice for the indication in question.	July 2015

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**
follitropin delta 12 micrograms, 36 micrograms and 72 micrograms solution for injection (Rekovelle®) *Ferring Pharmaceuticals Ltd* 07.08.17 *SMC Report No. 1269/17* NON SUBMISSION	NOT RECOMMENDED Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies such as an in vitro fertilisation or intracytoplasmic sperm injection cycle.	NOT RECOMMENDED	
fosfomycin (Monuril®) (oral) *Zambon Group*	Treatment of culture proven lower urinary tract infections caused by multiple antibiotic-resistant enterobacteriaceae. 	fosfomycin (Monuril®) has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions. A prescribing note will be added to the LJF.	September 2011
levonorgestrel 1500microgram tablet (Upostelle®) *Consilient Healthcare* 10.02.14 *SMC Report No. 938/14* PRODUCT UPDATE (abbreviated submission)	Accepted for use: levonorgestrel (Upostelle®) is accepted for use within NHS Scotland as emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. When the use of emergency contraception is indicated this is a slightly cheaper alternative to an existing preparation.	Included on the LJF for the indication in question. The choice of product will be reviewed with the Working Group.	February 2014
levonorgestrel 13.5mg intrauterine delivery system (Jaydess®) *Bayer* 13.04.15 *SMC Report No. 1036/15*	Accepted for use: levonorgestrel (Jaydess®) is accepted for use within NHS Scotland as contraception for up to 3 years. A phase III, open-label, randomised study confirmed the contraceptive efficacy of levonorgestrel 13.5mg intrauterine delivery system according to the Pearl Index.	Included on the LJF as a second choice for the indication in question.	September 2015
levonorgestrel (Levosert®) 20 micrograms/24 hours intrauterine delivery system *Actavis UK Ltd* 08.06.15 *SMC Report No. 1058/15* PRODUCT UPDATE (abbreviated submission)	Accepted for use: levonorgestrel (Levosert®) intrauterine delivery system is accepted for use within NHS Scotland. Indication under review: Contraception. Heavy menstrual bleeding. Levosert® may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception. Levosert® intrauterine delivery system (IUS) contains the same total amount of levonorgestrel with the same release profile as an existing levonorgestrel-containing IUS at a lower unit cost.	Not included on the LJF as clinicians do not support the formulary inclusion. The LJF choice is Mirena®.	November 2015

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**
magnesium sulphate, injection 5g in 10ml (50%) Martindale	Fetal neuroprotection in the context of preterm birth brain injury if delivery anticipated prior to 30 weeks gestation. 	Added to Additional list – Categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label) use of Medicines in NHS Lothian' - Specialist use only	March 2012
medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press) *Pfizer Ltd* 09.09.13 *SMC Report No. 896/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: medroxyprogesterone acetate injection (Sayana® Press) is accepted for use within NHS Scotland for long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year. In adolescents (12-18years), use of medroxyprogesterone acetate injection is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with medroxyprogesterone acetate injection during the critical period of bone accretion. Sayana® Press contains medroxyprogesterone acetate for subcutaneous injection at a similar cost to the existing deep intramuscular injection.	Included on the LJF for the indication in question. The LJF chapter will be reviewed.	August 2013
medroxyprogesterone acetate (Depo-Provera®) 150mg/ml injection	Contraception in the immediate postnatal period 	Included on the Additional List as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	July 2015
micronised progesterone (Utrogestan)	For the unlicensed use in luteal phase support for patients undergoing IVF 	Added to Additional list – Categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label) use of Medicines in NHS Lothian' - Specialist use only	June 2008 Superceded by SMC No. 935/13, below
micronised progesterone vaginal capsules 200mg (Utrogestan®) *Besins Healthcare (UK) Ltd* 08.05.17 *SMC Report No. 935/13* Patient Access Scheme	In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines.	May 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**
mifepristone 200mg tablet and misoprostol 0.2mg vaginal tablets combipack (Medabon®) *Sun Pharma* 10.11.14 *SMC Report No. 913/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: mifepristone tablet and misoprostol vaginal tablets combipack (Medabon®) is accepted for use within NHS Scotland for medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea. For patients in whom mifepristone and misoprostol is an appropriate choice of therapy, Medabon® provides the two components in a single pack at a lower cost than the individual components.	Not included on the LJF, pending protocol.	November 2014
mirabegron 25mg and 50mg prolonged-release tablets (Betmiga®) *Astellas Pharma Ltd* 13.05.13 *SMC Report No. 862/13*	Accepted for use: mirabegron (Betmiga®) is accepted for use within NHS Scotland for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome. Mirabegron was associated with modest treatment benefits over placebo in reducing symptoms associated with overactive bladder syndrome, including frequency and incontinence. Alternative treatments are available at a lower drug acquisition cost.	Included on the LJF as a prescribing note, for the indication in question.	August 2013
misoprostol, 200 microgram, vaginal delivery system (Mysodelle®) *Ferring Pharmaceuticals Ltd.* 13.10.14 *SMC Report No. 996/14*	Accepted for use: misoprostol (Mysodelle®) is accepted for use within NHS Scotland for induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated. Misoprostol vaginal delivery system significantly reduced the time to vaginal delivery, with a similar rate of caesarean section, compared with an active comparator.	Included on the additional list, specialist use, for the indication in question.	October 2015
nomegestrol acetate/estradiol (Zoely®) 2.5 mg/1.5 mg film-coated tablets Merck Sharp & Dohme Limited 08.07.13 *SMC Report No. 898/13* NON SUBMISSION	NOT RECOMMENDED: nomegestrol acetate/estradiol (Zoely®) is not recommended for use within NHS Scotland as oral contraception. 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	
norelgestromin, ethinylestradiol patch (Evra®) *Janssen-Cilag* 08.09.03 *SMC Report No. 48/03*	Restricted use: norelgestromin / ethinylestradiol (Evra®) patches have efficacy and an adverse-effect profile similar to combined oral contraceptives (COCs). There is some evidence of improved overall compliance with this preparation compared with COCs. It is more expensive than these oral contraceptives. Nevertheless, it is concluded that this preparation may be of benefit in the group of women who have demonstrated, or are deemed to be at, substantial risk of poor compliance with COCs. Use of Evra®should be restricted to this group of people.	Approved for use - added to the Additional List. Evra® is a contraceptive patch. It is more expensive than COCs and use should be restricted to patients who have poor compliance with COCs.	November 2003

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**
norethisterone (Micronor®, Noriday®)	Contraception in the immediate postnatal period. 	Included on the Additional List as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	July 2015
oestrogens, conjugated, bazedoxifene acetate (Duavive®) 0.45mg / 20mg modified-release tablets *Merck Sharp & Dohme Limited / Pfizer Limited* 16.01.17 *SMC Report No. 1220/17* NON SUBMISSION	NOT RECOMMENDED: oestrogens, conjugated, bazedoxifene acetate (Duavive®) is not recommended for use within NHS Scotland for the treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. The company 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	
oxybutynin 3.9mg/24h transdermal patch (Kentera®) *UCB Pharma Ltd* 08.08.05 *SMC Report No. 190/05*	Restricted use: oxybutynin transdermal patch (Kentera®) is accepted for restricted use within NHS Scotland for the treatment of urge incontinence and/or increased urinary frequency and urgency in patients with unstable bladder, restricted to patients who derive clinical benefit from oral oxybutynin but who experience intolerable anticholinergic side effects. It should be used in conjunction with non-pharmacological measures, including pelvic floor muscle exercises and bladder retraining. Transdermal oxybutynin appears to have similar efficacy to oral antimuscarinics and a lower rate of anticholinergic adverse events. However, patients have the additional effect of application site reactions, which in some patients lead to treatment discontinuation. Transdermal oxybutynin has a lower total cost than oral tolterodine, but a higher total cost than oral oxybutynin.	Added to the Formulary as a Prescribing Note, for patients who derive clinical benefit but suffer intolerable anticholinergic side effects from oral oxybutynin.	November 2005
pivmecillinam (Selexid®) *Leo Laboratories Ltd*	Treatment of culture proven lower urinary tract infections caused by multiple antibiotic-resistant enterobacteriaceae.	Added to the LJF as a prescribing note.	September 2011
progesterone 100mg vaginal tablets (Lutigest®) *Ferring Pharmaceuticals Ltd* 10.10.16 *SMC Report No. 1185/16* Patient Access Scheme	Accepted for use: progesterone (Lutigest®) is accepted for use within NHS Scotland as luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women. In women receiving luteal phase support during ART cycles, progesterone (Lutigest®) 100mg vaginal tablets administered three times daily were non-inferior to another progesterone preparation administered vaginally with respect to ongoing pregnancy rates at four to six weeks gestation and live birth rates. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of progesterone 100mg vaginal tablets. This advice is contingent on the continuing availability of the patient access scheme in Scotland or a list price that is equivalent or lower.	Not included on the LJF, because clinicians hae not responded to an invitation to apply for formulary inclusion for this medicine.	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**
propiverine hydrochloride 30mg modified release capsule (Detrunorm® XL) *Amdipharm PLC* 12.02.07 *SMC Report No. 340/07*	Accepted for use: propiverine hydrochloride 30mg modified release capsule (Detrunorm XL®) is accepted for use in NHS Scotland for the treatment of urinary incontinence, as well as urgency and frequency in patients who have idiopathic detrusor overactivity (overactive bladder). For patients for whom propiverine is appropriate it allows once-daily dosing, compared to twice daily dosing with an existing solid oral dose formulation, at no increased cost.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	June 2008
solifenacin succinate 5mg, 10mg (Vesicare®) *Yamanouchi* 07.11.05 *SMC Report No. 129/04* RESUBMISSION	Accepted for use: solifenacin succinate (Vesicare®) is accepted for use within NHS Scotland for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Solifenacin is effective in reducing symptoms associated with overactive bladder, including frequency, urgency and incontinence. It is associated with adverse events typical of antimuscarinic agents used in this condition. There are cheaper antimuscarinics available that would normally be used as first-line agents.	Added to the LJF as replacement for tolterodine.	October 2008
solifenacin succinate plus tamsulosin hydrochloride 6mg / 0.4mg modified release tablet (Vesomni®) *Astellas Pharma Ltd* 10.03.14 *SMC Report No. 945/14* PRODUCT UPDATE (abbreviated submission)	Accepted for use: solifenacin succinate plus tamsulosin hydrochloride 6mg / 0.4mg modified release tablet (Vesomni®) is accepted for use within NHS Scotland for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy. In patients for whom concomitant use of solifenacin succinate and tamsulosin hydrochloride is appropriate, Vesomni® allows administration of a single tablet at a lower cost compared to the individual components administered separately.	Included on the LJF as a prescribing note for patients who already receive a combination of solifenacin and tamsulosin, would benefit from a combination product and where patient compliance is an issue.	August 2014
tadalafil (Cialis®) *Lilly ICOS* 09.05.03 *SMC Report No.* 40/03	Accepted for use: tadalafil may be prescribed under the conditions of Schedule 11 and represents an alternative to other phosphodiesterase type 5 (PSE-5) inhibitors, primarily for patients for whom the longer duration of action represents a significant advantage. This drug is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) Regulations 1995.	Approved for use - added to the Formulary as second choice.	July 2003
tadalafil 2.5mg and 5mg film-coated tablets (Cialis®) *Lilly UK* 08.06.09 *SMC Report No. 554/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: tadalafil 2.5mg and 5mg tablets (Cialis®) are accepted for use in NHS Scotland for regular once-daily administration in patients with erectile dysfunction responding to an on-demand regimen of tadalafil who anticipate frequent use (at least twice weekly). Compared with this level of on-demand use, the low dose regular regimen is expected to be cost-neutral overall. Tadalafil represents an alternative to other phosphodiesterase type 5 inhibitors, primarily for patients for whom the longer duration of action represents a significant advantage. This drug is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) Regulations.	Added to the formulary as a prescribing note.	July 2009

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**
tadalafil (Cialis®) 5mg film coated tablets Eli Lilly and Company Limited 14.01.13 *SMC Report No. 849/12* NON SUBMISSION	NOT RECOMMENDED: tadalafil (Cialis®) is not recommended for use within NHS Scotland for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. 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	
tamsulosin (Flomaxtra XL®) *Yamanouchi Pharma Ltd* 05.08.05 *SMC Report No. 149/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: tamsulosin hydrochloride film-coated extended release tablets 400micrograms (equivalent to 367micrograms tamsulosin) are accepted for use in NHS Scotland for functional symptoms of benign prostatic hypertrophy as an alternative to modified release capsules.	Added to the Formulary - new formulation of existing drug. Plain formulation to be retained in the Formulary as patent expires in 2006.	October 2005
triptorelin 3.75mg (Gonapeptyl Depot®) *Ferring Pharmaceuticals Ltd* 08.05.06 *SMC Report No. 270/06* NON SUBMISSION	NOT RECOMMENDED: Gonapeptyl Depot® is not recommended for use within NHSScotland for symptomatic endometriosis confirmed by laparoscopy when suppression of the ovarian hormonogenesis is indicated to the extent that surgical therapy is not primarily indicated. 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	
triptorelin 11.25mg injection (Decapeptyl SR®) *Ipsen Ltd* 10.10.05 *SMC Report No. 207/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: triptorelin 11.25mg injection every 3 months (Decapeptyl SR®) is accepted for use within NHS Scotland for the treatment of endometriosis in patients for whom the use of triptorelin is appropriate and who would benefit from reduced frequency of administration compared with triptorelin 3mg injection every 4 weeks (Decapeptyl®).	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007
trospium chloride 20 mg film-coated tablets (Flotros®) *Galen Limited* 08.02.10 *SMC Report No. 600/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: trospium chloride (Flotros®) is accepted for use in NHS Scotland for symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder (e.g. idiopathic or neurologic detrusor overactivity). In patients for whom an immediate-release formulation of trospium chloride is an appropriate treatment, this preparation offers an alternative to an existing preparation at a lower cost.	'Not preferred' in Lothian as suitable alternatives exist.	March 2010

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**
ulipristal acetate, 30mg tablet (EllaOne®) *HRA Pharma UK Ltd* 08.02.10 *SMC Report No. 599/10*	Accepted for use: ulipristal acetate (EllaOne®) is accepted for use within NHS Scotland for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. When administered within the licensed time frame for ulipristal or an active comparator for emergency hormonal contraception, contraceptive efficacy with ulipristal was non-inferior to that with the comparator in individual studies and statistically superior in a meta-analysis of two studies. Other treatments are available at lower drug acquisition cost.	Added to the LJF as second choice for women presenting for emergency contraception.	May 2010
ulipristal acetate, 5mg, tablet (Esmya®) *PregLem Ltd.* 11.02.13 *SMC Report No. 834/13*	Accepted for use: ulipristal acetate (Esmya®) is accepted for use within NHS Scotland for pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months. Ulipristal was superior to placebo and non-inferior to a gonadotrophin releasing hormone (GnRH) agonist for reducing uterine bleeding in pre-operative women with uterine fibroids and excessive bleeding.	Included on the LJF as a prescribing note, for the indication in question. A new formulary section will be created to accommodate this treatment.	July 2013
ulipristal acetate, 5mg, tablet (Esmya®) *Gedeon Richter (Uk) Ltd* 08.02.16 *SMC Report No. 1128/16*	Accepted: ulipristal acetate (Esmya®) is accepted for use within NHS Scotland. Indication under review: for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. A phase III study demonstrated that treatment with the licensed dose of ulipristal acetate controlled uterine bleeding in approximately three-quarters of patients with symptomatic uterine fibroids after four intermittent treatment courses.	Not included on the LJF, pending protocol.	November 2016
urofollitropin (Fostimon®) *Pharmasure Ltd*	For use in IVF treatment	Added to the Formulary as second choice product. Specialist Use only.	April 2009
vardenafil (Levitra®) *GlaxoSmithKline / Bayer* 06.06.03 *SMC Report No. 47/03*	Accepted for use: vardenafil represents an acceptable alternative to other phosphodiesterase type 5 inhibitors for erectile dysfunction. This drug is likely to be subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of Schedule 11 of the National Health Service (General Medical Services) (Scotland) Regulations 1995.	'Not preferred' as effective alternatives available.	July 2003

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**
vardenafil 10mg orodispersible tablet (Levitra®) *Bayer Healthcare* 10.10.11 *SMC Report No. 727/11*	Restricted use: vardenafil orodispersible tablet (Levitra®) is accepted for restricted use within NHS Scotland. Treatment of erectile dysfunction (ED) in adult men. ED is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for vardenafil to be effective, sexual stimulation is required. SMC restriction: use is restricted to patients in whom an orodispersible tablet is an appropriate formulation. Vardenafil is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction in terms of National Health Service (General Medical Services) (Scotland) regulations. Two placebo controlled, studies have shown that vardenafil orodispersible is significantly better than placebo in the treatment of erectile dysfunction in men. No comparative evidence against other medicines for erectile dysfunction was presented.	Not included on the LJF because clinicians do not support the formulary inclusion. 'Not Preferred' as suitable alternatives exist.	May 2012