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

13 – Skin

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**
5-aminolaevulinic acid (as hydrochloride), 78mg/g, gel (Ameluz®) *Biofrontera Bioscience GmbH* 10.12.12 *SMC Report No. 811/12*	Accepted for use: 5-aminolaevulinic acid (as hydrochloride) (Ameluz®) is accepted for use within NHS Scotland for the treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2). In a multi-centre, randomised, observer-blind, controlled phase III study, 5-aminolaevulinic acid gel met pre-specified non-inferiority criteria compared with an alternative topical agent in terms of complete clearance of actinic keratosis lesions, 12 weeks after the last of up to two sessions of photodynamic therapy. The treatment difference was sufficient to demonstrate superiority over the alternative topical agent.	Included on the LJF as a prescribing note, Specialist Use only, for the indication in question.	October 2013
adalimumab, 40mg solution for injection (Humira®) *Abbott Laboratories Ltd* 09.06.08 *SMC Report No. 468/08*	Restricted use: adalimumab 40mg solution for injection (HumiraÒ) is accepted for restricted use within NHS Scotland for treatment of chronic plaque psoriasis in adult patients who failed to respond to or have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Its use should be restricted to patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score of ≥10 and a Dermatology Life Quality Index (DLQI) of >10. Adalimumab improves both signs and symptoms of psoriasis and quality of life compared to placebo and an active non-biological comparator. The manufacturer presented a sufficiently robust economic case to gain acceptance by the SMC for patients with severe disease who achieve a PASI 75 response from baseline at 16 weeks. Continuation of therapy beyond 16 weeks should be carefully reconsidered in patients not responding within this time period.	Added to the Additional List, for Specialist Use only.	May 2010
adalimumab (Humira®) 40 mg/0.8 ml solution injection (Humira®) *AbbVie Ltd* 13.07.15 *SMC Report No. 1068/15* PRODUCT UPDATE (abbreviated submission)	Restricted use: adalimumab (Humira®) is accepted for restricted use within NHS Scotland. Indication under review: Treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. SMC restriction: Patients with severe disease as defined by a total Psoriasis Area Severity Index (PASI) score of ≥10 and a Dermatology Life Quality Index (DLQI) of >10. Treatment with adalimumab in a paediatric population improves both signs and symptoms of psoriasis and quality of life.	Included on the Additional List, Specialist Use only, for the indication in question.	July 2015

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adalimumab 40mg/0.8mL solution for injection (Humira®) *AbbVie Ltd* 09.05.16 *SMC Report No. 1143/16*	Accepted for use: adalimumab (Humira®) is accepted for use within NHS Scotland. Indication under review: treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. Evidence from two double-blind, randomised studies demonstrated significant reductions in inflammatory lesions and no worsening of abscesses and draining fistulas at 12 weeks with adalimumab compared with placebo.	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 5th October 2017.	May 2017
adalimumab (Humira®) Pre-filled Pen, Pre-filled Syringe and Vial *AbbVie Limited* 11.07.16 *SMC Report No. 1173/16* NON SUBMISSION	NOT RECOMMENDED: adalimumab (Humira®) is not recommended for use within NHS Scotland for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy. (This licence extension relates to previous SMC advice (468/08). SMC has previously accepted adalimumab for restricted use for the treatment of chronic plaque psoriasis in adult patients who failed to respond to or have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. It is restricted to patients with severe disease as defined by a total Psoriasis Area Severity Index score of ≥10 and a Dermatology Life Quality Index of >10. (SMC 468/08). This advice remains valid. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL vial for paediatric use *AbbVie Ltd* 12.06.17 *SMC Report No. 1243/17* PRODUCT UPDATE (abbreviated submission)	Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.	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 5th October 2017.	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**
adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) *Galderma UK Ltd* 07.04.14 *SMC Report No. 682/11* RESUBMISSION Patient Access Scheme	Restricted use: adapalene 0.1%/benzoyl peroxide 2.5% gel (Epiduo®) is accepted for restricted use within NHS Scotland as cutaneous treatment of acne vulgaris when comedones, papules and pustules are present. SMC restriction: the treatment of mild to moderate facial acne when monotherapy with benzoyl peroxide or adapalene is not considered appropriate. In 12-week studies, adapalene 0.1%/benzoyl peroxide 2.5% gel was as effective as an alternative combination antibiotic treatment in reducing inflammatory lesions. However adapalene 0.1%/benzoyl peroxide 2.5% gel was less well tolerated in terms of local reactions. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of adapalene 0.1%/benzoyl peroxide 2.5% gel. 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 LJF as first choice, for the indication in question.	July 2016
alitretinoin 10mg, 30mg capsules (Toctino®) *Basilea Pharmaceuticals Ltd* 09.03.09 *SMC Report No. 538/09*	Accepted for use: alitretinoin (Toctino®) is accepted for use within NHS Scotland in adults who have severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids. Evidence is limited to a randomised placebo-controlled study where alitretinoin was superior to placebo in terms of the primary endpoint, Physician Global Assessment of response. It is recommended that alitretinoin is dispensed by a hospital-based pharmacy.	Added to the Additional List, for Specialist Use only. The above FC decision remaines unchanged.	July 2009 April 2013
apremilast 10mg, 20mg and 30mg film-coated tablets (Otezla®) *Celgene Ltd.* 08.06.15 *SMC Report No. 1052/15*	Accepted for use: apremilast (Otezla®) is accepted for use within NHS Scotland. Indication under review: for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). In two phase III, randomised, placebo-controlled studies in patients with moderate to severe plaque psoriasis, a significantly greater proportion of patients who received apremilast achieved at least 75% improvement in the Psoriasis Area and Severity Index (PASI) score at 16 weeks compared with those who received placebo.	Not included on the LJF, because clinicians do not support the formulary inclusion.	November 2016
azelaic acid 15% gel (Finacea®) *Valeant Pharmaceuticals Ltd* *Topical treatment of papulopustular rosacea* 07.05.07 *SMC Report No. 359/07*	Accepted for use: azelaic acid 15% gel (Finacea®) is accepted for use within NHS Scotland for the topical treatment of papulopustular rosacea. It shows equivalent efficacy at a lower cost compared to another topical preparation used for rosacea.	Added to the LJF as first choice for the treatment of papulopustular rosacea.	January 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**
betamethasone valerate 2.25mg medicated plaster (Betesil®) *Genus Pharmaceuticals* 09.08.10 *SMC Report No. 622/10*	NOT RECOMMENDED: betamethasone valerate medicated plaster (Betesil®) is not recommended for use within NHS Scotland. Indication under review: Treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Due to its particular pharmaceutical form, betamethasone medicated plaster is suitable for chronic plaque psoriasis localized in difficult to treat areas (e.g. knees, elbows and anterior face of the tibia on an area not greater than 5% of the body surface). In phase III studies in patients with mild to moderate plaque psoriasis, betamethasone medicated plaster was superior to non-occluded betamethasone cream, assessed using the psoriasis area and severity index score and psoriasis global assessment. However, the manufacturer did not submit a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
botulinum toxin type A (Azzalure®) *Galderma* 17.01.11 *SMC Report No. 679/11* NON SUBMISSION	NOT RECOMMENDED: botulinum toxin type A (Azzalure®) is not recommended for use within NHS Scotland. Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical "frown" lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication due to its cosmetic nature. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED:	
botulinum toxin Type A (Vistabel®) *Allergan* 17.01.11 *SMC Report No. 680/11* NON SUBMISSION	NOT RECOMMENDED: botulinum toxin Type A (Vistabel®) is not recommended for use within NHS Scotland. Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical "frown" lines between the eyebrows) in adult patients under 65 years and younger, when the severity of these lines has an important psychological impact on the patient. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication due to its cosmetic nature. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
botulinum toxin type A (Bocouture®) *Merz Pharma* 07.03.11 *SMC Report No. 695/11* NON SUBMISSION	NOT RECOMMENDED: botulinum toxin type a (Bocouture ®) is not recommended for use within NHS Scotland. Indication under review: for the temporary improvement in the appearance of moderate to severe glabellar lines (vertical lines between the eyebrows) seen at frown, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication due to its cosmetic nature. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

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brimonidine, 3.3mg/g (0.33%) gel equivalent to 5mg/g brimonidine tartrate (Mirvaso®) *Galderma* 12.01.15 *SMC Report No. 1016/14*	Restricted use: brimonidine (Mirvaso®) is accepted for restricted use within NHS Scotland for the symptomatic treatment of facial erythema of rosacea in adult patients. SMC restriction: for use in patients with moderate to severe persistent facial erythema associated with rosacea. Two identical phase III studies demonstrated that brimonidine 0.33% gel significantly reduced erythema compared with vehicle gel in patients with rosacea.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion.	March 2015
calcipotriol and betamethasone dipropionate ointment (Dovobet®) *Leo Pharma* 12.12.05 *SMC Report No. 09/02* RESUBMISSION	Restricted use: calcipotriol/betamethasone dipropionate ointment (Dovobet®) is accepted for restricted use within NHS Scotland for the initial topical treatment of stable plaque psoriasis. Short term comparisons have shown that the combination is more effective than either component as monotherapy and that it is cost effective compared to alternative therapies. Its use is restricted to physicians experienced in treating inflammatory skin disease. Dovobet® contains a potent steroid, the use of which carries risks of destabilising psoriasis and side effects from prolonged use. The duration of treatment should not exceed four weeks.	Added to the LJF as a prescribing note. Treatment restricted to 4 weeks maximum, treatment by Specialists only. Repeat courses should not be used.	December 2007
calcipotriol and betamethasone dipropionate, 50 micrograms/g + 500 microgram/g gel (Xamiol®) *LEO Pharma* 10.08.09 *SMC Report No. 559/09*	Accepted for use: calcipotriol and betamethasone dipropionate scalp gel, (Xamiol®) is accepted for use within NHS Scotland for the topical treatment of scalp psoriasis. Short-term comparisons have shown that the combination is more effective than either component used as monotherapy.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication.	August 2010
calcipotriol 50micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®) Leo Pharma 12.09.16 *SMC Report No. 1182/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: calcipotriol and betamethasone cutaneous foam (Enstilar®) is accepted for use within NHS Scotland topical treatment of psoriasis vulgaris in adults. Enstilar® cutaneous foam is another licensed formulation of calcipotriol / betamethasone and may be associated with a small budget impact.	Routinely available in line with national guidance. Included on the LJF as a prescribing note, for General Use.	May 2017
calcitriol 3micrograms/g ointment (Silkis®) *Galderma (UK) Ltd* 09.05.03 *SMC Report No. 43/03*	Accepted for use: calcitriol 3micrograms/g ointment (Silkis®) is recommended for general use within NHS Scotland. Limited data indicate comparable efficacy and similar or better tolerability of calcitriol compared to existing topical vitamin D analogues in the treatment of mild to moderate plaque psoriasis in adults. As calcitriol ointment is a substitute for existing medicines that have similar or increased costs, it is assumed that the net budget impact to the NHS will be minimal.	Added to the Formulary as first choice drug because it is thought to be better tolerated than current therapies. A replacement for topical calcipotriol (Dovonex®) for the treatment of mild to moderate plaque psoriasis.	January 2004

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chlorhexidine gluconate 2% in 70% isopropyl alcohol cutaneous solution (ChloraPrep®) *CareFusion*	For disinfection of the skin prior to invasive procedures.	Added to the Additional List as a first-line treatment, for Specialist Use only.	November 2013
clindamycin 1% and benzoyl peroxide 5% gel (Duac® Once Daily) *Stiefel Laboratories* 13.04.04 *SMC Report No. 92/04*	Restricted use: Duac® Once Daily is accepted for restricted use within NHS Scotland for the treatment of mild to moderate acne vulgaris. It should be considered after using benzoyl peroxide monotherapy and only when the addition of a topical antibiotic is deemed clinically necessary. Compared to other combination products, Duac® offers the advantage of once daily use at no additional cost.	Added to the Additional List. Duac® should be considered after benzoyl peroxide monotherapy and only when addition of topical antibiotic is deemed clinically necessary. Added to the LJF as a prescribing note for the treatment of mild to moderate acne vulgaris.	June 2004 November 2009
clindamycin 1% / tretinoin 0.025% gel (Treclin®) *Meda Pharmaceuticals Ltd.* 08.12.14 *SMC Report No. 1010/14* PRODUCT UPDATE (abbreviated submission) Patient Access Scheme	Accepted for use: clindamycin 1% / tretinoin 0.025% gel (Treclin®) is accepted for use within NHS Scotland for the topical treatment of acne vulgaris when comedones, papules and pustules are present in patients 12 years or older. For use in patients for whom a topical combination of clindamycin and tretinoin is an appropriate choice of therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of clindamycin 1% / tretinoin 0.025% gel. 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 LJF as a prescribing note, for the indication in question.	December 2014
clobetasol propionate 0.05% cutaneous foam (Clarelux®) *3M Health Care Ltd* 10.07.06 *SMC Report No. 280/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: clobetasol propionate 0.05% cutaneous foam (Clarelux®) is accepted for use within NHS Scotland for short-course treatment of steroid responsive dermatoses of the scalp such as psoriasis, which do not respond satisfactorily to less potent steroids. It offers an alternative to other scalp applications of clobetasol propionate at a similar cost (depending on the rate of application).	New formulation of a drug already included in the Formulary.	October 2007
clobetasol propionate 0.05% shampoo (Etrivex®) *Galderma (UK) Limited* 11.08.08 *SMC Report No. 434/07* RESUBMISSION	Accepted for use: clobetasol propionate 0.05% shampoo (Etrivex®) is accepted for use within NHS Scotland for the topical treatment of moderate scalp psoriasis in adults. Comparison of clobetasol propionate 0.05% shampoo to another clobetasol formulation demonstrated non-inferiority and costs are similar.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	November 2009

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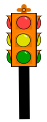
diclofenac sodium 3% gel (Solaraze®) *Shire Pharmaceuticals*	Actinic keratosis	Added to the Formulary as joint first choice for patients with small non tender diffuse actinic keratoses. Care should be taken to avoid confusion with Voltarol Emulgel® (non-formulary) which contains a different concentration of diclofenac to relieve musculoskeletal pain.	November 2005
efalizumab (Raptiva®) 125 mg as powder and solvent for 100mg/ml injection *Genentech, in partnership with Serono. Developed by XOMA.* 07.02.05 *SMC Report No. 146/04* Superseded by NICE MTA103	Treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or have a contra-indication to, or are intolerant to other systemic therapies, including ciclosporin, methotrexate and PUVA (photochemotherapy). SMC - not recommended for use. NICE - recommends for use (NICE technology appraisal guidance 103. Etanercept and efalizumab for adults with psoriasis. July 2006. www.nice.org.uk/page.aspx?o=TA103) NHS QIS www.nhshealthquality.org/nhsqis advises that this NICE appraisal is as valid for Scotland as for England and Wales and that the guidance on efalizumab supersedes the advice issued by the Scottish Medicines Consortium 10 December 2004.	Added to the Additional List, for Specialist Use only. Marketing authorisiation withdrawn	October 2006 April 2009
eflornithine 11.5% cream (Vaniqa®) *Shire Pharmaceutical Contracts Ltd* 12.09.05 *SMC Report No. 159/05* RESUBMISSION	Restricted use: eflornithine 11.5% cream (Vaniqa®) is accepted for restricted use within NHS Scotland for the treatment of facial hirsutism in women. It is restricted to use in women for whom alternative drug therapy is ineffective, contra-indicated or considered inappropriate. Eflornithine 11.5% cream, as a topical treatment, may offer advantages over existing therapy for some women as it avoids the risks associated with systemic therapies.	'Not preferred' in Lothian for the treatment of facial hirsutism in women - pending additional information from clinicians, requested by FC.	July 2006
emulsifying ointment BP 25% w/w in coconut oil BP	Treatment of scalp dermatitis, psoriasis, keratosis. 	Added to the LJF as a prescribing note. Emulsifying ointment BP 25% w/w in coconut oil BP has been categorised **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2013
etanercept (Enbrel®) *Wyeth* *NICE MTA 103* *July 2006*	Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or have a contra-indication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA (photochemotherapy) NICE - recommends for use (NICE technology appraisal guidance 103. Etanercept and efalizumab for adults with psoriasis. July 2006. www.nice.org.uk/page.aspx?o=TA103) NHS QIS www.nhshealthquality.org/nhsqis advises that this NICE appraisal is as valid for Scotland as for England and Wales and that the guidance on efalizumab supersedes the advice issued by the Scottish Medicines Consortium 10 December 2004.	Added to the Additional List, for Specialist Use only.	October 2006

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etanercept (Enbrel®) *Wyeth Pharmaceuticals* 07.09.09 *SMC Report No. 570/09* PRODUCT UPDATE (abbreviated submission)	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. It should be used only when the following criteria are met: -The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10; -The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments; -Etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Etanercept has previously been accepted for use in this indication in adults in NHS Scotland as NHS QIS advised that NICE Multiple Technology Appraisal No 103 is valid for Scotland. Etanercept is also listed in the British National Formulary for Children as one of a number of drugs affecting the immune response available for treatment of severe refractory psoriasis.	Added to the Additional List. For Specialist Use only.	September 2009
etanercept 10mg and 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®) *Pfizer Ltd* 14.05.12 *SMC Report No. 781/12* PRODUCT UPDATE (abbreviated submission)	Restricted use: etanercept (Enbrel®) is accepted for restricted use within NHS Scotland for the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. SMC restriction: - The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10; - The psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments; - etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks. Etanercept has previously been accepted for use in this indication in adults in NHS Scotland as NHS Health Improvement Scotland advised that NICE Multiple Technology Appraisal No 103 is valid for Scotland. Etanercept has previously been accepted for restricted use by SMC in adolescents and children from the age of 8 years. Etanercept is also listed in the British National Formulary for Children 2011-2012 as one of a number of drugs affecting the immune response available for treatment of severe refractory psoriasis.	Included on the Additional List for the indication in question. Specialist Use only. Added to the Additional List. Specialist Use only.	May 2012
fluorouracil 0.5% / salicylic acid 10% cutaneous solution (Actikerall®) *Almirall S.A.* 10.10.11 *SMC Report No. 728/11*	Accepted for use: fluorouracil 0.5% / salicylic acid 10% cutaneous solution (Actikerall®) is accepted for use within NHS Scotland. The topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients. Fluorouracil 0.5% / salicylic acid 10% cutaneous solution was superior to another topical treatment for the histological clearance of a specified target actinic keratosis lesion.	Included on the LJF as a prescribing note for the indication in question.	November 2013

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imiquimod 5% cream (Aldara®) *Meda Pharmaceuticals Ltd* 12.05.08 *SMC Report No. 385/07* RESUBMISSION	Restricted use: imiquimod (Aldara®) is accepted for restricted use within NHS Scotland for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate. It should be restricted to use in patients after specialist advice. Imiquimod was more effective than vehicle in clearing actinic keratosis lesions.	Included on the LJF as a prescribing note, for Specialist Initiation, for the indication in question.	November 2013
imiquimod (Zyclara®) 3.75% cream *Meda Pharmaceuticals* . 09.12.13 *SMC Report No. 934/13* NON SUBMISSION	NOT RECOMMENDED: imiquimod (Zyclara®) is not recommended for use within NHS Scotland for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate. 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	
infliximab 100mg powder for intravenous infusion (Remicade®) *Schering-Plough UK Ltd* 07.05.0 *SMC Report No. 318/06*	Restricted use: infliximab (Remicade®) is accepted for restricted use within NHS Scotland for the treatment of severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant of other systemic therapy including ciclosporin, methotrexate or psoralen ultraviolet A (PUVA). Infliximab, compared to placebo, improves both signs and symptoms of psoriasis and quality of life in adults with plaque psoriasis. The economic case was demonstrated when used for patients with severe psoriasis who achieve a PASI 75 response or a 50% reduction in PASI and a 5 point reduction in DLQI from baseline at 10 weeks. It is one of several biologic interventions for the treatment of plaque psoriasis, some of which have lower drug acquisition costs.	Added to the Additional List.	November 2008
ivermectin, 10mg/g, cream (Soolantra®) *Galderma (U.K) Ltd* 07.12.15 *SMC Report No. 1104/15*	Restricted: ivermectin (Soolantra®) is accepted for restricted use within NHS Scotland. Indication under review: topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients. SMC restriction: the treatment of moderate to severe inflammatory lesions of rosacea where a topical treatment is considered appropriate. A phase III, randomised study demonstrated ivermectin 10mg/g cream was significantly superior to an antimicrobial cream at reducing the percentage of inflammatory lesions from baseline to week 16. The submitting company did not submit evidence for SMC assessment for use in patients with mild papulopustular rosacea, therefore SMC cannot recommend ivermectin 10mg/g cream for use in this sub-population.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	March 2016

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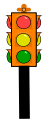
ixekizumab 80mg solution for injection (Taltz®) *Eli Lilly and Company Ltd.* 10.04.17 *SMC Report No. 1223/17* Patient Access Scheme	For moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.	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
methyl aminolevulinate 160mg/g cream (Metvix®) *Galderma (UK) Ltd* 10.11.03 *SMC Report No. 50/03* RESUBMISSION	Accepted for use: The evidence of efficacy for Metvix® for the treatment of thin or non-hyperkeratotic and non-pigmented actinic keratosis on the face and scalp is not strong. The health economic evidence is incomplete, though it suggests similar costs to the alternative treatment (cryotherapy). However, Metvix® appears to have a place for treatment of those patients when other therapies are considered less appropriate and should be delivered by a dermatologist experienced in this therapy.	Included on the LJF as a prescribing note.	September 2015
miconazole 2% cream (Daktarin®) *Cilag Ltd and McNeil Products Ltd* Local formulary process	For the treatment of breast and nipple thrush in lactating women. 	Routinely available in line with local or regional guidance. Included on the LJF as a prescribing note, for General Use. Classified as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Included on the LJF as a prescribing note, General Use. Classified as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2017
NexoBrid® gel *MedlWound Germany* Local formulary process	For the removal of eschar in adults with deep partial and full thickness thermal burns up to a maximum of 15% total body surface area.	Routinely available in line with local or regional guidance. Included on the Additional List, Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question. To be used by trained healthcare professionals in specialist burn centres.	January 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**
omalizumab 150mg solution for injection (Xolair®) *Novartis Pharmaceuticals UK Ltd* 12.01.15 *SMC Report No 1017/14* Patient Access Scheme	Restricted use: omalizumab (Xolair®) is accepted for restricted use within NHS Scotland as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment. SMC restriction: use in adults and adolescents with chronic spontaneous urticaria who have an inadequate response to combination therapy with H1 antihistamines, leukotriene receptor antagonists (LTRA) and H2 antihistamines, used according to current treatment guidelines. The addition of omalizumab to combination therapy with H1-antihistamines, and/or leukotriene receptor antagonists and/or H2-antihistamines was more effective than placebo in reducing the weekly itch severity score (ISS) at 12 weeks. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of omalizumab. 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 pending protocol.	March 2015
pimecrolimus 1% cream (Elidel®) *Novartis* 09.08.04 *SMC Report No. 35/03* FOLLOWING INDEPENDENT REVIEW PANEL ASSESSMENT Superseded by NICE MTA 82	Treatment of signs and symptoms of mild-to-moderate atopic dermatitis. SMC - not recommended for use. NICE - recommends for use (NICE technology appraisal guidance 82. Tacrolimus and pimecrolimus for atopic eczema. August 2004. www.nice.org.uk/page.aspx?o=TA82) NHS QIS www.nhshealthquality.org/nhsqis advises that NICE technology appraisal 82 recommendations are as valid for Scotland as for England and Wales.	Added to the Additional List, for Specialist Use only.	January 2005
propranolol	Treatment of childhood haemangioma causing functional problems or disfigurement. 	Added to the Additional List, for Specialist Use only. Propranolol for the treatment of childhood haemangioma causing functional problems or disfigurement 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 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**
secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) *Novartis Pharmaceuticals* 08.06.15 *SMC Report No. 1054/15* Patient Access Scheme	Restricted use: secukinumab (Cosentyx®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC restriction: for patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments. Secukinumab was superior to placebo and to a tumour necrosis factor (TNF) antagonist for improving symptoms of patients with moderate to severe plaque psoriasis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of secukinumab. It 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.	July 2016
silver alginate dressing (Silvercel®) *Systagenix Wound Management Ltd.* Local formulary process	Treatment of colonised and infected wounds in adult patients at the Spittal Street Centre (Substance Misuse Directorate).	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
tacrolimus ointment 0.1% and 0.03% (Protopic®) *Fujisawa* 04.10.02 SMC Report No. 12/02	Restricted use: tacrolimus offers a treatment option for adults with atopic dermatitis intolerant of or unresponsive to conventional treatments, and for children aged 2 years or over who are unresponsive to conventional topical therapies. It is a potent immunosuppressant which can be absorbed systemically following topical application, and there are unresolved concerns about possible adverse effects arising from this. Its use should therefore be considered prior to oral therapy when it is deemed that other appropriate options for topical therapy have been exhausted. Its use should be initiated and supervised by dermatologists within secondary care who have experience of treating atopic dermatitis using immunomodulatory therapy. In order to facilitate future investigation of long-term effects of the use of tacrolimus ointment, it is advised that a register of recipients should be established and maintained.	Approved for use - added to the Formulary as third line treatment of severe atopic dermatitis. FC decision remains unchanged.	August 2005 April 2013
tacrolimus 0.03% ointment (Protopic®) *Astellas Pharma Ltd* 12.04.10 *SMC Report No. 608/10*	Restricted use: tacrolimus 0.03% ointment (Protopic®) is accepted for restricted use within NHS Scotland. Licensed indication under review: for maintenance treatment of moderate to severe atopic dermatitis in children (aged 2 to15 years) for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected). SMC Restriction: Use is restricted to initiation by doctors with a specialist interest and experience in treating atopic dermatitis using immunomodulatory therapy (this can include General Practitioners. Twice weekly maintenance therapy with tacrolimus ointment resulted in reduced disease exacerbations when compared to intermittent use only to treat disease exacerbations.	Included on the LJF for the indication in question. The SCP will be amended to include maintenance treatment.	April 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**
tacrolimus 0.1% ointment (Protopic®) *Astellas Pharma Ltd* 12.04.10 *SMC Report No. 609/10*	Restricted use: tacrolimus 0.1% ointment (Protopic®) is accepted for restricted use within NHS Scotland. Licensed indication under review: the maintenance treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in adult patients (≥16 years) experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected). SMC Restriction: Use is restricted to initiation by doctors with a specialist interest and experience in treating atopic dermatitis using immunomodulatory therapy (this can include General Practitioners). Twice weekly maintenance therapy with tacrolimus ointment resulted in reduced disease exacerbations when compared to intermittent use only to treat disease exacerbations.	Included on the LJF for the indication in question. The SCP will be amended to include maintenance treatment.	April 2013
ustekinumab, 45mg solution for injection (Stelara®) *Janssen-Cilag Ltd* 08.02.10 *SMC Report No. 572/09* Patient Access Scheme	Restricted use: ustekinumab (Stelara®) is accepted for restricted use within NHS Scotland for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen and UVA treatment (PUVA). Significantly more patients treated with ustekinumab achieved at least 75% improvement in their Psoriasis Area and Severity Index (PASI) score at week 12, compared with those treated with a tumour necrosis factor alpha antagonist. Continued treatment should be restricted to patients who achieve a PASI 75 response within 16 weeks. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ustekinumab. This SMC advice is dependent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist Use only.	May 2010
ustekinumab 45mg solution for injection and prefilled syringe (Stelara®) *Janssen Ltd* 11.01.16 *SMC Report No.1115/15* PRODUCT UPDATE (abbreviated submission)	Restricted use: ustekinumab (Stelara®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. SMC restriction: continued treatment should be restricted to patients who achieve at least 75% improvement in their Psoriasis Area and Severity Index (PASI 75) within 16 weeks. Ustekinumab has previously been accepted for restricted use in adults for this indication. For the small number of adolescent patients weighing >100kg that require a dose of 90mg, a 90mg prefilled syringe is available at the same price as the 45mg prefilled syringe.	Included on the additional list, specialist use only.	March 2016
Versiva® XC dressing	Use in moderate to high exudating, sloughy or granulating wounds to replace the combination of Aquacel and Allevyn (adhesive or non-adhesive)	Added to the LJF as a prescribing note, alternative first choice when Aquacel and Alevyn are used in combination.	December 2010