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

10 – Musculoskeletal and Joint Diseases

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**
abatacept, 250mg powder for concentrate for solution (Orencia®) *Bristol Myers Squibb Pharmaceuticals Ltd* August 2009 *NICE MTA 195* *Supersedes SMC Report No. 400/07*	abatacept (Orencia®) in combination with methotrexate is recommended as a treatment option only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDS, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.	Added to the Additional List, for Specialist Use only.	March 2011
abatacept (Orencia®) 250mg powder for concentrate for solution for injection *Bristol-Myers Squibb Pharmaceuticals Ltd* 07.11.11 SMC Report No. 618/10 PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015 Patient Access Scheme	NICE MTA 373 states; abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for abatacept, people 6 years and older whose disease has responded inadequately to other disease-modifying anti-rheumatic drugs (DMARDs) including at least 1 tumour necrosis factor (TNF) inhibitor Abatacept is recommended only if the company provides it with the discounts agreed in the patient access schemes for these technologies. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Added to the Additional List, Specialist Use only. SMC advice superseded by NICE MTA373, December 2015 FC decision still valid.	March 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**
abatacept 250mg powder for concentrate for solution for infusion (Orencia®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 08.04.13 *SMC Reprot No. 719/11* RESUBMISSION Patient Access Scheme SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Included on the Additional List, Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA375, February 2016 There is a material difference between SMC and NICE advice. FC decision to be reviewed.	July 2013
abatacept 125mg/mL solution for subcutaneous injection in a pre-filled syringe (Orencia®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 12.08.13 SMC Report No. 888/13 PRODUCT UPDATE (abbreviated submission) Patient Access Scheme SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Included on the Additional List, Specialist Use only for the indication in question. ClickJet® Pre-Filled Pens are now available, they are approved for use as above. SMC advice superseded by NICE MTA375, February 2016 There is a material difference between SMC and NICE advice. FC decision to be reviewed.	August 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**
abatacept (Orencia®) 125mg solution for injection (pre-filled syringe) 125mg solution for injection in pre-filled pen 250mg powder for concentrate for solution for infusion *Bristol-Myers Squibb Pharmaceutical Limited* 13.03.17 SMC Report No. 1230/17 NON SUBMISSION	Treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.	NOT RECOMMENDED	April 2017
adalimumab (Humira®) *Abbott Laboratories* 08.12.03 SMC Report No. 81/03 SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Added to the Formulary, for Specialist Use only. Adalimumab is the third TNF-antagonist licensed for the treatment of rheumatoid arthritis. Efficacy is similar but has advantage over etanercept in dosing regimen. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	January 2004 February 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**
adalimumab 40mg pre-filled syringe (Humira®) *Abbott Laboratories Ltd* 11.12.06 *SMC Report No. 300/06* Superseded by NICE MTA143 Superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response	Added to the Additional List, for Specialist Use only. SMC advice superseded by NICE MTA383 There is a material difference between SMC and NICE advice. FC decision to be reviewed.	October 2008 February 2016
adalimumab 40mg pre-filled syringe for subcutaneous injection (Humira®) *Abbott* 12.12.05 SMC Report No. 218/05	Accepted for use: adalimumab (Humira®) is accepted for use within NHS Scotland for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Adalimumab improves symptoms of arthritis and psoriasis and may slow the progression of joint damage in patients with active psoriatic arthritis.	Added to the Formulary, for Specialist Use only. Adalimumab is an alternative for patients with psoriatic arthritis which is not controlled with two DMARDs or etanercept.	January 2006
adalimumab 40mg solution for injection (Humira®) *Abbott Laboratories* 09.02.09 *SMC Report No. 533/09* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015	NICE MTA 373 states; abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD Adalimumab is recommended, within marketing authorisation, as option for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) whose disease has responded inadequately to, or who are intolerant of, conventional therapy. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Added to Additional List, Specialist Use only. SMC advice superseded by NICE MTA373. FC decision still valid.	August 2009 December 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**
adalimumab (Humira®), 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use *Abbott Laboratories* 07.11.11 *SMC Report No. 738/11* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015	NICE MTA 373 states; abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD Adalimumab is recommended, within marketing authorisation, as option for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) whose disease has responded inadequately to, or who are intolerant of, conventional therapy. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Added to the Additional List, for Specialist Use only. SMC advice superseded by NICE MTA373. FC decision still valid.	March 2012 December 2015
adalimumab, 40mg/0.8mL, solution for injection (Humira®) *AbbVie Ltd* 08.04.13 *SMC Report No. 858/13* SMC advice superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response	Included on the Additional List, Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA383. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	July 2013 February 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**
adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®) *AbbVie Limited* 08.07.13 *SMC Report No. 881/13* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015	NICE MTA 373 states; abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD Adalimumab is recommended, within marketing authorisation, as option for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) whose disease has responded inadequately to, or who are intolerant of, conventional therapy. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Included on the Additional List, Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA373. FC decision still valid.	July 2013 December 2015
adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (HUMIRA®) *AbbVie Ltd* 11.05.15 *SMC Report No. 1050/15* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015	NICE MTA 373 states; abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD Adalimumab is recommended, within marketing authorisation, as option for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) whose disease has responded inadequately to, or who are intolerant of, conventional therapy. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Included on the Additional List, Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA373. FC decision still valid.	July 2015 December 2015
alemtuzumab, 12mg, concentrate for solution for infusion (Lemtrada®) *Genzyme* 07.07.14 *SMC Report No. 959/14*	Accepted for use: alemtuzumab (Lemtrada®) is accepted for use within NHS Scotland for adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features. Two phase III studies comparing alemtuzumab with interferon beta-1a in treatment-naive (CARE-MS I) and treatment-experienced (CARE-MS II) patients with relapsing remitting multiple sclerosis both showed a statistically significant relative decrease in relapse rate of 55% and 49% respectively in favour of alemtuzumab. There was a significant reduction in the risk of sustained accumulation of disability over 6 months of 42% in CARE-MS II, but for CARE-MS-I, this was not statistically significant.	Included on the Additional List, for Specialist Use only, for the indication in question. Clinicians wishing to use in patients with highly active disease.	November 2014

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
amifampridine 10mg tablet, as phosphate (Firdapse®) *BioMarin UK Ltd* 13.08.12 *SMC Report No. 660/10*	NOT RECOMMENDED: amifampridine phosphate (Firdapse®) is not recommended for use within NHS Scotland for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. There are no clinical data for amifampridine phosphate and efficacy has been extrapolated from studies of amifampridine base (3,4-diaminopyridine), to which amifampridine phosphate has been accepted to be bioequivalent by the European Medicines Agency. In randomised controlled studies in patients with LEMS, 3,4-diaminopyridine treatment was associated with greater improvement in muscle strength and neuromuscular transmission than placebo. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
anakinra, human recombinant interleukin-1 receptor antagonist (Kineret®) *Amgen* 08.11.02 *SMC Report No. 05/02* REVIEW ASSESSMENT	*NOT RECOMMENDED:* anakinra, human recombinant interleukin-1 receptor antagonist (Kineret®) is not recommended for use in NHS Scotland. Rheumatoid Arthritis. The company have produced no additional data to indicate a susceptible target population for this biological product which does not appear to be as effective as competitor products, and is not particularly cost effective.	NOT RECOMMENDED	
apremilast 10mg, 20mg, 30mg tablets (Otezla®) *Celgene Ltd.* 08.06.15 *SMC Report No. 1053/15*	Restricted use: apremilast (Otezla®) is accepted for restricted use within NHS Scotland. Indication under review: alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. SMC restriction: for use in adult patients with active PsA who have had an inadequate response with at least two prior DMARD therapies or who are intolerant to such therapies. In three phase III, randomised, placebo-controlled studies in patients with active psoriatic arthritis, a significantly greater proportion of patients who received apremilast achieved at least 20% improvement in the American College of Rheumatology response criteria (ACR 20) at 16 weeks compared with those who received placebo.	Included on the LJF, Specialist Use only, for the indication in question.	May 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**
ataluren 125mg, 250mg, 1,000mg granules for oral suspension (Translarna®) *PTC Therapeutics Ltd* 11.04.16 *SMC Report No. 1131/16*	NOT RECOMMENDED: ataluren (Translarna®) is not recommended for use within NHS Scotland. Indication under review: Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older. In a phase IIb, randomised, double-blind study the absolute difference in mean change in 6-minute walking distance from baseline to week 48 for ataluren 40mg/kg/day compared to placebo was 30 metres in the intent-to-treat analysis. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting	NOT RECOMMENDED	
Avonex® Liquid (Interferon beta 1a) *Biogen Ltd* 10.11.03 *SMC Report No. 58/03* PRODUCT UPDATE (abbreviated submission	Restricted use: Avonex® Liquid (Interferon beta 1a) is accepted for restricted use within NHS Scotland. Avonex is a liquid formulation which replaces a powder formulation of the same strength that requires reconstitution. It is supplied at the same price. This product is used for the treatment of selected ambulatory patients with relapsing-remitting multiple sclerosis under the provision of a risk-sharing scheme between the Scottish Executive and the manufacturer.	A new formulation of a drug already included in the Formulary. This is a new formulation of interferon beta which is used for the treatment of multiple sclerosis (Specialist Use only) in selected patients as part of the MS risk-sharing scheme.	November 2003
baricitinib 2mg and 4mg film-coated tablet (Olumiant®) *Eli Lilly and Company Ltd* 11.09.17 *SMC Report No 1265/17*	Accepted for restricted use within NHS Scotland. Indication under review: treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Baricitinib may be used as monotherapy or in combination with methotrexate. SMC restriction: In patients with severe disease (a disease activity score [DAS28] greater than 5.1) that has not responded to intensive therapy with a combination of conventional DMARDs. In patients with severe disease inadequately controlled by a TNF antagonist, it may be used in patients ineligible to receive rituximab. Baricitinib, compared with placebo and with a tumour necrosis factor (TNF) antagonist, significantly improved signs and symptoms of RA in patients with an inadequate response to conventional DMARDs and, compared with placebo, in patients who had an inadequate response to a TNF antagonist. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of baricitinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Formulary classification not yet decided – waiting for information from clinicans.	

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**
canakinumab (Ilaris®) 150 mg powder for solution for injection *Novartis Pharmaceuticals Ltd* 10.06.13 *SMC Report No. 883/13* NON SUBMISSION	NOT RECOMMENDED: canakinumab (Ilaris®) is not recommended for use within NHS Scotland for symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not 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	
canakinumab (Ilaris®) 150mg powder for solution for injection *Novartis Pharmaceuticals UK Limited* 11.11.13 *SMC Report No. 926/13* NON SUBMISSION	NOT RECOMMENDED: canakinumab (Ilaris®) is not recommended for use within NHS Scotland for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate. 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	
canakinumab (Ilaris®) 150mg powder for solution for injection *Novartis Pharmaceuticals UK Ltd* 07.11.16 *SMC Report No. 1210/16* NON SUBMISSION	NOT RECOMMENDED: canakinumab (Ilaris®) is not recommended for use within NHS Scotland for the treatment of active Still's disease including Adult-Onset Still's Disease who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate. 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	
cannabinoid oromucosal spray (Sativex ®) *Bayer plc.* 11.04.11 *SMC Report No: 703/11* NON SUBMISSION	NOT RECOMMENDED: cannabinoid oromucosal spray (Sativex ®) is not recommended for use within NHS Scotland. Indication under review: as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. 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	
celecoxib (Celebrex®) *Pharmacia Limited* 10.09.07 *SMC Report No. 410/07* NON SUBMISSION	NOT RECOMMENDED: celecoxib (Celebrex®) is not recommended for use within NHS Scotland for ankylosing spondylitis. 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 NHS Scotland.	NOT RECOMMENDED	
celecoxib (Celebrex®) Pharmacia	Treatment of osteoarthritis and rheumatoid arthritis in patients who are in need of NASID therapy and are at high risk of gastrointestinal (GI) side effects.	Not preferred as suitable alternatives are available.	July 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**
certolizumab pegol, 200 mg/mL solution for injection (prefilled syringe) (Cimzia®) UCB Pharma Ltd 11.10.10 *SMC Report No. 590/09* RESUBMISSION Patient Access Scheme SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Added to the LJF as first choice. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	January 2011 February 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**
certolizumab pegol 200mg/mL solution for injection in pre-filled syringe (Cimzia®) *UCB Pharma UK* 12.05.14 *SMC Report No: 960/14* Patient Access Scheme SMC advice superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.	Included on the LJF as a first choice drug, for Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA383. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	July 2014 February 2016
certolizumab pegol, 200mg/mL, solution for injection in pre-filled syringe (Cimzia®) *UCB Pharma UK* 07.07.14 *SMC Report No. 973/14* Patient Access Scheme	Restricted use: certolizumab pegol (Cimzia®): is accepted for restricted use within NHS Scotland in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. SMC restriction: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination. In a phase III, randomised, placebo-controlled study in patients with active psoriatic arthritis, significantly more patients who received certolizumab pegol achieved at least 20% response on the American College of Rheumatology criteria (ACR 20) at 12 weeks compared with those who received placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab pegol. 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 first choice drug, for Specialist Use only, for the indication in question.	July 2014

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
certolizumab pegol (Cimzia®) 200 mg solution for injection *UCB Pharma Limited* 09.05.16 *SMC Report No. 1155/16* NON SUBMISSION	NOT RECOMMENDED: certolizumab pegol (Cimzia®) is not recommended for use within NHS Scotland. Indication under review: Treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. 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	
collagenase clostridium histolyticum 0.9mg powder and solvent for solution for injection (Xiapex®) *Pfizer Ltd* 14.05.12 *SMC Report No. 715/11* RESUBMISSION	Restricted use: collagenase clostridium histolyticum (Xiapex®) is accepted for restricted use within NHS Scotland for the treatment of Dupuytren's contracture in adult patients with a palpable cord. SMC restriction: restricted to use as an alternative to limited fasciectomy in adult patients with Dupuytren's contracture of moderate severity (as defined by the British Society for Surgery of the Hand (BSSH), with a palpable cord and up to two affected joints per hand, who are suitable for limited fasciectomy, but for whom percutaneous needle fasciotomy is not considered a suitable treatment option. Collagenase clostridium histolyticum compared to placebo significantly reduces primary joint contracture in adults with Dupuytren's contracture and palpable cord. The cost-effectiveness of collagenase clostridium histolyticum relative to percutaneous needle fasciotomy was not demonstrated.	Included on the Additional List, for Specialist Use only.	August 2012
collagenase clostridium histolyticum (Xiapex®) *Swedish Orphan Biovitrum Ltd* 11.05.15 *SMC Report No.1059/15* NON SUBMISSION	NOT RECOMMENDED: collagenase clostridium histolyticum (Xiapex)® is not recommended for use within NHS Scotland as treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. 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	
dimethyl fumarate 120mg, 240mg gastro-resistant hard capsules (Tecfidera®) *Biogen Idec Ltd* 07.04.14 *SMC Report No.886/13* Patient Access Scheme	Accepted for use: dimethyl fumarate (Tecfidera®) is accepted for use within NHS Scotland for treatment of adult patients with relapsing remitting multiple sclerosis. Two phase III, placebo-controlled studies demonstrated significantly superior efficacy for dimethyl fumarate compared to placebo for the primary end-points of proportion of patients relapsed at two years (in one study) and the annualised relapse rate (in the other study). This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dimethyl fumarate. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, for Specialist Use only, for the indication in question.	May 2014
etanercept (Enbrel®) *Wyeth Pharmaceuticals* 12.07.04 *SMC Report No. 107/04*	Accepted for use: etanercept (Enbrel®) is accepted for use within NHS Scotland for the treatment of active and progressive psoriatic arthritis in adults. It is the first drug to be licensed for this indication and not only improves symptoms of arthritis and psoriasis, but may slow the progression of joint damage (at least over a period of one year).	Added to the LJF, for Specialist Use only.	August 2004

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**
etanercept 25mg vial of powder for subcutaneous injection (Enbrel®) *Wyeth* 07.11.05 *SMC Report No. 212/05* Superseded by NICE MTA 143 Superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response	Added to the LJF, for Specialist Use only. SMC advice superseded by NICE MTA383. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	January 2006 February 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**
etanercept 50mg subcutaneous injection (Enbrel®) for ankylosing spondylitis *Wyeth Pharmaceuticals* 11.09.06 *SMC Report No. 303/06* PRODUCT UPDATE (abbreviated submission) Superseded by NICE MTA 143 Superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.	New formulation of a drug already included in the Formulary. SMC advice superseded by NICE MTA383. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	October 2007 February 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**
etanercept 50mg subcutaneous injection (Enbrel®) for rheumatoid arthritis *Wyeth Pharmaceuticals* 11.09.06 *SMC Report No. 305/06* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	New formulation of a drug already included in the Formulary. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	October 2007 February 2016
etanercept 10mg and 25mg powder and sterile water for solution for injection for paediatric use (Enbrel®) *Pfizer Ltd* 14.05.12 *SMC Report No. 782/12* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015	NICE MTA 373 states: abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for etanercept, people 2 years and older whose disease has responded inadequately to, or who are intolerant of, methotrexate, and Etanercept is recommended, within marketing authorisation, as option for treating enthesitis-related JIA, that is, for people 12 years and older (etanercept) whose disease has responded inadequately to, or who are intolerant of, conventional therapy. Etanercept is recommended, within its marketing authorisation, as an option for treating psoriatic JIA, that is, in people aged 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Included on the Additional List for the indication in question. Specialist Use only. Added to the Additional List. Specialist Use only. SMC advice superseded by NICE MTA373. FC decision still valid.	May 2012 December 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**
etanercept 10mg and 25mg powder and solvent for solution for injection for paediatric use, 25mg and 50mg solution for injection in pre-filled syringe, 50mg solution for injection in pre-filled pen (Enbrel®) *Pfizer Ltd* 11.02.13 *SMC Report No. 842/13* PRODUCT UPDATE (abbreviated submission) SMC advice superseded by NICE MTA373, December 2015	NICE MTA 373 states: abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for etanercept, people 2 years and older whose disease has responded inadequately to, or who are intolerant of, methotrexate, and Etanercept is recommended, within marketing authorisation, as option for treating enthesitis-related JIA, that is, for people 12 years and older (etanercept) whose disease has responded inadequately to, or who are intolerant of, conventional therapy. Etanercept is recommended, within its marketing authorisation, as an option for treating psoriatic JIA, that is, in people aged 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Included on the Additional List, Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA373. FC decision still valid.	January 2013 December 2015
etanercept (Benepali®)	For the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyarthropathy.	Included on the LJF as first choice, Specialist use only, for the indication in question.	April 2016
etoricoxib (Arcoxia®) *Merck Sharp & Dohme Ltd* 07.03.03 *SMC Report No. 31/03*	Accepted for use: etoricoxib is recommended for use within NHS Scotland. Its use should be in accordance with guidance issued by the National Institute for Clinical Excellence (NICE) for COX-2 selective NSAIDs in the treatment of osteoarthritis (OA) and rheumatoid arthritis (RA). Etoricoxib is effective in the symptomatic treatment of OA and RA. It is also effective in the treatment of acute gouty arthritis. It should be used for patients at high risk of gastro-intestinal adverse-effects to non-selective NSAIDs. In common with other COX-2 selective NSAIDs, etoricoxib is associated with less gastrointestinal adverse-effects than non-selective NSAIDs, but the relative risks of cardiovascular events in such patients are unclear. There is no evidence that etoricoxib has advantages or disadvantages compared with other COX-2 selective NSAIDs.	Non-Formulary - 'Not preferred' as effective alternatives available.	July 2003
etoricoxib 60mg, 90mg and 120mg tablets (Arcoxia®) *Merck Sharpe & Dohme Ltd* 09.10.06 SMC Report No. 313/06 PRODUCT UPDATE (abbreviated submission)	Accepted for use: etoricoxib 60mg, 90mg and 120mg tablets (Arcoxia®) are accepted for use in NHS Scotland for the symptomatic relief of osteoarthritis, rheumatoid arthritis and the pain and signs of inflammation associated with gouty arthritis, in patients for whom the use of etoricoxib is appropriate, taking account of current advice on the place in therapy of specific inhibitors of cyclo-oxygenase-2 (COX-2). The new tablet formulation is smaller than the existing formulation at the same cost per dose.	'Not preferred' as suitable alternatives exist.	October 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**
etoricoxib (Arcoxia®) *Merck Sharpe and Dohme* 07.09.09 SMC Report No. 576/09 NON SUBMISSION	NOT RECOMMENDED: etoricoxib (Arcoxia®) is not recommended for use within NHSScotland for the treatment of ankylosing spondylitis. 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	
fampridine 10mg prolonged-release tablets (Fampyra®) *Biogen Idec Ltd* 07.11.16 *SMC Report No. 789/12*	NOT RECOMMENDED: fampridine (Fampyra®) is not recommended for use within NHS Scotland for the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS [expanded disability status scale] 4 to 7). In two short-term, randomised, double-blind, phase III studies, significantly higher proportions of patients in the fampridine than placebo groups were considered responders, as assessed using the timed 25 foot walk test. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®) *Novartis Pharmaceuticals UK Ltd* 10.09.12 *SMC Report No. 763/12* RESUBMISSION Patient Access Scheme	Restricted use: fingolimod (Gilenya®) is accepted for restricted use within NHS Scotland as single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: • Patients with high disease activity despite treatment with a beta-interferon. These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least one relapse in the previous year while on therapy, and have at least nine T2-hyperintense lesions in cranial magnetic resonance imaging (MRI) or at least one gadolinium-enhancing lesion. A "non-responder" could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. or • Patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. SMC restriction: restricted to use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. Fingolimod reduced the annualised relapse rate significantly more than a beta-interferon in patients with clinically active RRMS. An indirect comparison also demonstrated similar efficacy to another disease modifying therapy in established use in RRMS. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fingolimod. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Included on the LJF for the indication in question, Specialist Use only.	November 2012

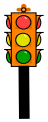
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
fingolimod, 0.5mg, hard capsules (Gilenya®) *Novartis Pharmaceuticals UK* 13.10.14 *SMC Report No. 992/14* Patient Access Scheme	Restricted use: fingolimod (Gilenya®) is accepted for restricted use within NHS Scotland as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups: • Patients with high disease activity despite treatment with at least one disease modifying therapy. or • Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. SMC restriction: For use in patients with rapidly evolving severe relapsing remitting multiple sclerosis. SMC has previously published advice concerning patients with high disease activity despite treatment with beta-interferon. Fingolimod reduced the annualised relapse rate significantly more than a beta-interferon in patients with clinically active relapsing remitting multiple sclerosis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fingolimod. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	November 2014
fingolimod 0.5mg hard capsules (Gilenya®) *Novartis Pharmaceuticals UK* 13.04.15 *SMC Report No. 1038/15* *Patient Access Scheme*	Accepted for use: fingolimod (Gilenya®) is accepted for use within NHS Scotland as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: - Patients with high disease activity despite treatment with at least one disease modifying therapy. In patients who had high disease activity despite prior disease modifying therapy in the previous year, fingolimod reduced the annualised relapse rate compared with another disease modifying therapy. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of fingolimod. This advice is contingent upon the continuing availability of the patient access scheme, or a list price that is equivalent or lower, in NHS Scotland.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion	May 2015
glatiramer acetate 40mg/mL solution for injection prefilled syringes (Copaxone®) *Teva UK Limited* 07.12.15 *SMC Report No. 1108/15* PRODUCT UPDATE (abbreviated submission)	Accepted: glatiramer acetate 40mg/mL (Copaxone®) is accepted for use within NHS Scotland. Indication under review: treatment of relapsing forms of multiple sclerosis (MS). This new formulation of glatiramer actetate (40mg/ml) given three times a week costs the same as the currently available formulation (glatiramer acetate 20mg/ml) that is given daily.	Included on the LJF as a prescribing note for the indication in question.	December 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**
glucosamine (as hydrochloride), 625mg tablets (Alateris®) *William Ransom & Son plc* 09.06.08 *SMC Report No. 471/08*	NOT RECOMMENDED: glucosamine (as hydrochloride) (Alateris®) is not recommended for use within NHS Scotland for relief of symptoms in mild to moderate osteoarthritis of the knee. No direct clinical trial evidence of the efficacy and safety of this specific product is available. Randomised controlled trials of other formulations of glucosamine hydrochloride indicate little or no benefit over placebo in improving symptoms in patients with osteoarthritis of the knee. In addition, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
glucosamine sulphate, 1,500mg powder for oral solution (Glusartel®) *Rottapharm Madaus* 08.08.11 *SMC Report No. 647/10* RESUBMISSION	NOT RECOMMENDED: glucosamine sulphate (Glusartel®) is not recommended for use within NHS Scotland. Indication under review: relief of symptoms in mild to moderate osteoarthritis of the knee. In a placebo- and active-comparator study, glucosamine sulphate 1,500mg once daily was significantly better than placebo in the treatment of symptoms associated with osteoarthritis of the knee. Overall the submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
glucosamine sulphate (Dolenio®) *Blue Bio Pharmaceuticals Ltd* 08.08.11 *SMC Report No: 729/11* NON SUBMISSION	NOT RECOMMENDED: glucosamine sulphate (Dolenio®) is not recommended for use within NHS Scotland. Indication under review: symptomatic treatment of mild to moderate osteoarthritis (OA) of the knee. 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	
golimumab, 50mg, solution for injection in pre-filled pen (auto-injector) or pre-filled syringe (Simponi®) *Merck, Sharp & Dohme* 09.07.12 *SMC Report No. 674/11* RESUBMISSION	Restricted use: golimumab (Simponi®) is accepted for restricted use within NHS Scotland. Indication under review: Alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. SMC restriction: golimumab is restricted to use in patients whose disease has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is also restricted to use at a dose of 50mg only. Golimumab has demonstrated efficacy when compared with placebo in patients with active psoriatic arthritis who have had an inadequate response to DMARDs or non-steroidal anti-inflammatory drugs (NSAIDs). The economic case was demonstrated for golimumab when used at a dose of 50mg. The economic case was not demonstrated for the 100mg dose of golimumab.	Not included on the LJF because clinicians do not support the formulary inclusion.	August 2012

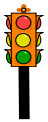
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®) *MSD* 12.09.11 *SMC Report No. 721/11* SMC advice superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.	Added to the Additional List, Specialist Use only SMC advice superseded by NICE MTA383. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	January 2012 February 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**
golimumab 50mg solution for injections prefilled pen (auto-injector) or pre-filled syringe (Simponi®) *MSD Ltd* 07.11.11 *SMC Report No. 733/11* SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.	Not included on the LJF because clinicians do not support the formulary inclusion. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	May 2012 February 2016
golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®) *Merck Sharp & Dohme Limited* 08.02.16 *SMC Report No. 1124/16* Patient Access Scheme	Accepted use: golimumab (Simponi®) is accepted for use within NHS Scotland. Indication under review: treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). Golimumab, compared to placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of golimumab. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	March 2016
golimumab (Simponi®) 50 mg solution for injection®) *Merck Sharp & Dohme Limited* 10.10.16 *SMC Report No. 1199/16* NON SUBMISSION	NOT RECOMMENDED: golimumab (Simponi®) is not recommended for use within NHS Scotland in combination with methotrexate for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with methotrexate. 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**
ibuprofen melts 400mg	Pre-operative dosing where no NSAIDs have been administered in advance, and occasional post-operative use in patients unable to swallow ibuprofen tablets	Added to the Additional List.	October 2007
ibuprofen topical 5% gel Local formulary process	For the treatment of acute musculoskeletal pain.	Routinely available in line with local or regional guidance. Included on the LJF as a prescribing note, for Specialist Use only. Included on the LJF as a prescribing note, for Specialist Use only, for the indication in question.	March 2017
indomethacin 50mg vial containing powder and solvent for injection (Liometacin®) *Chiesi Farmaceutici*	Treatment of ventilated patients with acute liver failure and raised uncontrollable intracranial pressure 	Added to the Additional List. Indomethacin 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 2009
infliximab 100mg vial of powder for intravenous infusion (Remicade®) *Schering-Plough* 10.10.05 *SMC Report No. 101/04* RESUBMISSION Superseded by NICE MTA 143 Superseded by NICE MTA383, February 2016	NICE MTA383 states: adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units, and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial response.	Added to the Formulary as second choice for the treatment of ankylosing spondylitis, for Specialist Use only. SMC advice superseded by NICE MTA383. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	January 2006 February 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**
infliximab (Remicade®) powder for reconstitution 100mg vial *Schering-Plough*	For the treatment of refractory juvenile idiopathic arthritis (JIA), uveitis associated with JIA and idiopathic uveitis in children and young people. 	Added to the Additional List, for Specialist Use only. Infliximab (Remicade®) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	May 2014
infliximab, 100mg, powder for concentrate for solution for infusion (Remsima®) *Celltrion Healthcare Hungary Kft.* 09.03.15 *SMC Report No. 1006/14* SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop	Included on the LJF, for specialist use only, for the indication in question. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	September 2015 February 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**
infliximab, 100mg, powder for concentrate for solution for infusion (Inflectra®) *Hospira UK Ltd.* 09.03.15 *SMC Report No. 1007/14* SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop	Not included on the LJF, for the indication in question. LJF choice is Remsima. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice.	May 2015 February 2016
interferon beta-1a (Rebif®) *Merck Serono* 12.11.12 *SMC Report No. 825/12* NON SUBMISSION	NOT RECOMMENDED: interferon beta-1a (Rebif®) is not recommended for use within NHS Scotland for patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis 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	
interferon beta-1b 250micrograms/mL for solution for injection (Betaferon®) *Schering Health Care Ltd* 12.02.07 *SMC Report No. 345/07*	NOT RECOMMENDED: interferon beta-1b (Betaferon®) is not recommended for use within NHS Scotland for the treatment of patients with a single demyelinating event with an active inflammatory process, severe enough to warrant treatment with intravenous corticosteroids, where alternative diagnoses are excluded and who are determined to be at high risk of developing clinically definite multiple sclerosis. Although interferon beta-1b has been found to increase the time to clinically definite multiple sclerosis over 2 years, the long-term effect on the disease process remains unknown. The economic case has not been demonstrated.	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**
ketoprofen/omeprazole, 100mg/20mg; 200mg/20mg modified release capsules (Axorid®) *Meda Pharmaceuticals* 12.07.10 *SMC Report No. 606/10*	Accepted for use: ketoprofen/omeprazole (Axorid®) is accepted for use within NHS Scotland. Licensed indication under review: the symptomatic treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis in patients with a previous history or who are at risk of developing NSAID associated gastric ulcers, duodenal ulcers and gastroduodenal erosions in whom continued treatment with ketoprofen is essential. Studies in healthy volunteers demonstrated the bioequivalence of this combination product to the reference products, modified-release ketoprofen and omeprazole. Other nonsteroidal anti-inflammatory drugs can be co-prescribed with proton pump inhibitors at lower cost.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2012
methotrexate injection 10mg/mL (Metoject®) pre-filled syringes 7.5mg, 10mg, 15mg, 20mg, 25mg *Medac UK* 11.12.06 *SMC Report No. 332/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: methotrexate injection 10mg/mL (Metoject®) is accepted for use in NHS Scotland for the treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs (DMARD) is indicated. For patients in whom parenteral methotrexate is appropriate, this is the first licensed parenteral formulation for this indication.	Added to the Additional List. Now available as 50mg/mL pre-filled syringes.	July 2009
methotrexate 50mg/ml pre-filled syringe (Metoject®) *Medac*	Inlammatory diseases eg non-classified polyarthritis 	Added to the Additional List. Methotrexate 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.	September 2009
methotrexate injection 10mg/mL (Metoject®) pre-filled syringes 7.5mg, 10mg, 15mg, 20mg, 25mg *Medac UK* 12.10.09 *SMC Report No. 573/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: methotrexate injection 50mg/ml (Metoject®) is accepted for use in NHS Scotland for the treatment of severe recalcitrant disabling psoriasis which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients. For patients in whom parenteral methotrexate is appropriate, this is the first licensed parenteral formulation for this indication.	Added to the Additional List. Now available as 50mg/mL pre-filled syringes.	September 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**
methotrexate 50mg/mL solution for injection (Metoject®) prefilled syringes 12.5mg, 17.5mg, 22.5mg, 27.5mg and 30mg *Medac GmbH* 08.08.11 *SMC Report No: 724/11* PRODUCT UPDATE (abbreviated submission)	Accepted for use: methotrexate 50mg/mL solution for injection (Metoject®) is accepted for use within NHS Scotland. Indication under review: polyarthritic forms of severe active juvenile idiopathic arthritis, when the response to non-steroidal anti-inflammatory drugs has been inadequate. For patients in whom treatment with disease modifying drugs is indicated and parenteral administration of methotrexate is appropriate, this adds to the range of pre filled syringes available. The Scottish Medicines Consortium has previously accepted methotrexate for the treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs is indicated. Methotrexate injection is listed in the British National Formulary for Children 2010 -11 for the treatment of juvenile idiopathic arthritis.	Added to the Additional List.	August 2011
methotrexate (Zlatal®) pre-filled syringe 25mg/mL	Tretment of rheumatoid arthiritis, psoriatic arthritis and juvenile idiopathic arthritis.	Included on the LJF as second choice, for the indication in question.	July 2016
naproxen/esomeprazole 500mg/20mg modified release tablets (Vimovo®) *AstraZeneca UK* 07.11.11 *SMC Report No. 734/11*	NOT RECOMMENDED: naproxen 500mg/esomeprazole 20mg (Vimovo®) is not recommended for use within NHS Scotland the symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS), in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient. Studies have demonstrated that combined naproxen/esomeprazole was associated with a lower incidence of endoscopic gastric ulcers than NSAID alone and similar improvements in pain and functioning compared to a cyclo-oxygenase-2 selective inhibitor. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
naproxen 250mg effervescent tablets (Stirlescent®) *Stirling Anglian Pharmaceuticals Ltd.* 13.06.16 *SMC Report No: 1154/16* PRODUCT UPDATE (abbreviated submission)	Restricted use: naproxen 250mg effervescent tablets (Stirlescent®) are accepted for restricted use within NHS Scotland for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults. SMC restriction: use in patients unable to swallow naproxen tablets. Naproxen 250mg effervescent tablets (Stirlescent®) have demonstrated bioequivalence to naproxen 250mg tablets. The effervescent tablet formulation provides an alternative for patients who cannot swallow tablets. They are more expensive than generic naproxen tablets but cost less than unlicensed naproxen oral liquid (special formulation). Another non-steroidal anti-inflammatory drug is available in dispersible form and may cost less than naproxen when the higher dose of naproxen is required.	Not included in the LJF, because the Board decision is that the medicine does not represent sufficient benefit to other comparator medicines to treat the condition in question.	July 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**
natalizumab 300mg concentrate for solution for infusion (Tysabri®) *Biogen Idec Ltd* 10.09.07 *SMC Report No. 329/06* RESUBMISSION	Accepted for use: natalizumab (Tysabri®) is accepted for restricted use within NHS Scotland as single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) only in patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year and with one or more gadolinium-enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load compared with a previous MRI. In a post-hoc sub-group analysis of the pivotal trial, which included patients with rapidly evolving severe RRMS, it was associated with a significant reduction in the annualised relapse rate and the probability of sustained progression of disability over two years compared with placebo.	Added to the formulary for Specialist Use only by a Consultant Neurologist.	January 2008
natalizumab (Tysabri®) 300 mg concentrate for solution for infusion *Biogen Idec Ltd* 09.06.14 *SMC Report No. 979/14* NON SUBMISSION	NOT RECOMMENDED: natalizumab (Tysabri®) is not recommended for use within NHS Scotland as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate. SMC has previously not recommended natalizumab for use in patients with high disease activity despite treatment with beta-interferon. The marketing authorisation has now been extended to include use in patients with high disease activity despite treatment with glatiramer. 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. SMC has previously accepted natalizumab (Tysabri®) for restricted use as a single disease modifying therapy in highly active RRMS in patients with rapidly evolving severe RRMS and this advice remains in place.	NOT RECOMMENDED	
peginterferon 63, 94 and 125 microgram solution for injection in pre-filled syringe (Plegridy®) *Biogen Idec Ltd.* 12.01.15 *SMC Report No. 1018/14*	Accepted for use: peginterferon-beta-1a (Plegridy®) is accepted for use within NHS Scotland in adult patients for the treatment of relapsing remitting multiple sclerosis. Peginterferon-beta-1a, compared with placebo, improved annualised relapse rate in adults with relapsing remitting multiple sclerosis.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2015
prednisolone 10mg/mL oral solution and prednisolone 5mg tablets	For the steroid responsive inflammatory conditions in children.	Included on the LJF as a first choice, Specialist Use only, for the indication in question.	August 2016
prednisone (Lodotra®) 1 mg, 2 mg and 5 mg modified-release tablets *Napp Pharmaceuticals* 13.02.12 SMC Report No. 771/12 NON SUBMISSION	NOT RECOMMENDED: prednisone (Lodotra®) is not recommended for use within NHS Scotland for the treatment of moderate to severe, active rheumatoid arthritis in adults particularly when accompanied by morning stiffness. 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	

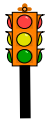
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
rituximab 100mg/10mL, 500mg/50mL solution for intravenous infusion (MabThera®) *Roche* 13.11.06 *SMC Report No. 323/06*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland in combination with methotrexate for treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARDs) including one or more tumour necrosis factor (TNF) inhibitor. It is restricted to use by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis. Rituximab in combination with methotrexate improves signs and symptoms and quality of life and prevents joint damage compared to methotrexate, in adults with rheumatoid arthritis who have had an inadequate response to methotrexate and an inadequate response or intolerance to at least one TNF-antagonist. Treatment should only be repeated in patients who continue to achieve an American College of Rheumatology (ACR) response of at least 20. Rituximab is cost effective if the average dosing interval for those patients who respond to initial treatment does not fall below six months.	To remain on the Additional List, for Specialist Use only (now a licensed indication).	January 2007
rituximab 100mg, 500mg solution for infusion (MabThera®) *Roche Products Limited* 09.09.13 *SMC Report No. 894/13*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland in combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). SMC restriction: to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide. One course of rituximab (an intravenous infusion weekly for four weeks) was non-inferior to three to six months of oral cyclophosphamide for the proportion of patients achieving remission at six months. The study was conducted in patients with severe proteinase 3- or myeloperoxidase-antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis who were treatment-naïve or previously treated.	Included on the Additional List, Specialist Use only, for the indication in question.	October 2013 and November 2013
secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®) *Novartis Pharmaceuticals* 11.07.16 *SMC Report No. 1159/16* Patient Access Scheme	Accepted for use: secukinumab (Cosentyx®) is accepted for use within NHS Scotland for the treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy. Secukinumab, compared with placebo, significantly improved symptoms of AS in adults with active disease inadequately controlled with non-steroidal anti-inflammatory drugs. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of secukinumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, Specialist Use only, for the indication in question.	October 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**
secukinumab 150mg solution for injection in pre-filled pen and pre-filled syringe (Cosentyx®) *Novartis Pharmaceuticals UK Limited* 08.08.16 *SMC Report No. 1167/16* Patient Access Scheme	Restricted use: secukinumab (Cosentyx®) is accepted for restricted use within NHS Scotland alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. SMC restriction: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination. In phase III, randomised, placebo-controlled studies in patients with active psoriatic arthritis, a significantly greater proportion of patients who received secukinumab achieved at least 20% improvement in the American College of Rheumatology response criteria (ACR20) at 24 weeks compared with those who received placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of secukinumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Included on the LJF as first choice, Specialist Use only, for the indication in question.	November 2016
teriflunomide, 14mg, film-coated tablets (Aubagio®) *Genzyme Ltd.* 10.03.14 *SMC Report No. 940/14* Patient Access Scheme	Restricted use: teriflunomide (Aubagio®) is accepted for restricted use within NHS Scotland for the treatment of adults with relapsing remitting multiple sclerosis (MS). SMC restriction: as an alternative to treatment with interferon beta or glatiramer acetate. Teriflunomide is not expected to be used for the treatment of patients with highly active disease. In two phase III, randomised, double-blind, placebo-controlled, parallel-group studies in adult patients with relapsing MS, teriflunomide significantly reduced the annualised relapse rate. In a phase III, randomised, single-blind, parallel-group study, teriflunomide showed similar efficacy to interferon beta. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of teriflunomide. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, for Specialist Use only, for the indication in question.	May 2014

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**
tocilizumab, 20mg/ml concentrate for solution for injection (RoActemra®) *Roche* 18.01.10 *SMC Report No. 593/09* SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop	Added to the Additional List, for Specialist Use Only. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	May 2010 February 2016
tocilizumab, 20mg/mL concentrate for solution for infusion (RoActemra®) *Roche Products Limited* 13.02.12 *SMC Report No. 754/12* Patient Access Scheme	Accepted for use: tocilizumab (RoActemra®) is accepted for use within NHS Scotland for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate. Tocilizumab was superior to placebo in reducing disease activity and fever in patients with persistent active systemic juvenile idiopathic arthritis despite treatment with NSAIDs and corticosteroids. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	Included on the Additional List, for Specialist Use only, for the indication in question.	January 2014

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
tocilizumab, 20mg/mL, concentrate for solution for infusion (RoActemra®) *Roche Products Limited* 10.09.12 *SMC Report No. 774/12* RESUBMISSION Patient Access Scheme SMC advice superseded by NICE MTA375, February 2016	NICE MTA375 states: adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, all in combination with methotrexate, are recommended as options for treating rheumatoid arthritis, only if: • disease is severe, that is, a disease activity score (DAS28) greater than 5.1 and • disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs) and • the companies provide certolizumab pegol, golimumab, abatacept and tocilizumab as agreed in their patient access schemes. Adalimumab, etanercept, certolizumab pegol or tocilizumab can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained. Start treatment with the least expensive drug (taking into account administration costs, dose needed and product price per dose). This may need to be varied for some people because of differences in the mode of administration and treatment schedules. People whose treatment with adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab or abatacept is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop	Included on the Additional List, Specialist Use only for the indication in question pending local protocol. SMC advice superseded by NICE MTA375. There is a material difference between SMC and NICE advice. FC decision to be reviewed.	October 2012 February 2016
tocilizumab, 20mg/mL concentrate for infusion (RoActemra®) *Roche Products Ltd* 13.01.14 *SMC Report No. 930/13* PRODUCT UPDATE (abbreviated submission) Patient Access Scheme SMC advice superseded by NICE MTA373, December 2015 Patient Access Scheme	NICE MTA 373 states: abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is: • for tocilizumab, people 2 years and older whose disease has responded inadequately to previous therapy with methotrexate. Tocilizumab is recommended only if the company provide them with the discounts agreed in the patient access schemes for these technologies. When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.	Included on the Additional List, for Specialist Use only, for the indication in question. SMC advice superseded by NICE MTA373. FC decision still valid	January 2014 December 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**
tocilizumab, 162mg, solution for injection in pre-filled syringe (RoActemra®) *Roche Products Ltd.* 11.08.14 *SMC Report No. 982/14* Patient Access Scheme	Restricted use: tocilizumab (RoActemra®) is accepted for restricted use within NHS Scotland in combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. Tocilizumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate. SMC restriction: tocilizumab is restricted to use in accordance with current eligibility and continuation rules for biologic therapies in rheumatoid arthritis. A phase III, randomised, double-blind, parallel-group study in adult patients with rheumatoid arthritis demonstrated that subcutaneous tocilizumab was non-inferior to tocilizumab intravenous infusion for the primary outcome of proportion of patients who achieved an American College of Rheumatology 20% response. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of subcutaneous tocilizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, for Specialist Use only, for the indication in question.	August 2014
tocilizumab (RoActemra®) 20 mg/ml concentrate for solution for infusion *Roche* 08.12.14 *SMC Report No. 1020/14* NON SUBMISSION	NOT RECOMMENDED: tocilizumab (RoActemra®) is not recommended for use within NHS Scotland for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. 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	
tocilizumab (RoActemra®) 162mg solution for injection in pre-filled syringe *Roche Products Ltd* 10.10.16 *SMC Report No. 1201/16* NON SUBMISSION	NOT RECOMMENDED: tocilizumab (RoActemra®) is not recommended for use within NHS Scotland for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication / setting. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
triamcinolone hexacetonide 20mg/mL suspension for injection *Intrapharm Laboratories Limited* 09.11.15 *SMC Report No. 1103/15* PRODUCT UPDATE (abbreviated submission)	Accepted: triamcinolone hexacetonide is accepted for use within NHS Scotland. Indication under review: juvenile idiopathic arthritis (JIA). This submission relates to a new licence extension for JIA where previously an unlicensed preparation has been used. This is the first intra-articular corticosteroid licensed for JIA.	Included on the LJF, for the indication in question.	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**
ustekinumab 45mg solution for injection in pre-filled syringe (Stelara®) *Janssen-Cilag Ltd* 10.03.14 *SMC Report No. 944/14*	Restricted use: ustekinumab (Stelara®) is accepted for restricted use within NHS Scotland, alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate. SMC restriction: for use in patients with active psoriatic arthritis who have failed on, or are unsuitable for, treatment with an anti-TNF drug. Significantly more patients with active psoriatic arthritis who were treated with ustekinumab achieved at least 20% response on American College of Rheumatology criteria (ACR 20) at 24 weeks compared with those treated with placebo.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2014
zoledronic acid 4mg/5mL vial *Dr Reddy's Laboratories Ltd.*	Treatment of patients with osteogenesis imperfecta, juvenile idiopathic osteoporosis, recurrent fractures due to osteopaenia. 	Included on the LJF as a first choice drug, for Specialist Use only. Classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	August 2016