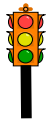
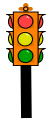
Recommendations from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice, NICE MTA advice, (FAF3) unlicensed and off-label medicines and (FAF2) medicines not considered by SMC

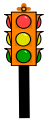
8 - Malignant Disease and Immunosuppression

In alphabetical order

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
5-aminolevulinic acid hydrochloride (Gliolan®) *Medac*	To help guide resection of Glioblastomas	Added to the Additional List, for Specialist Use only.	December 2013
5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®) *Biofrontera Bioscience GmbH* 07.08.17 *SMC Report No. 1260/17*	NOT RECOMMENDED Treatment of superficial and / or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and / or poor cosmetic outcome in adults.	NOT RECOMMENDED	
abiraterone acetate 250mg tablets (Zytiga®) *Janssen-Cilag Ltd* 13.08.12 *SMC Report No. 764/12* RESUBMISSION Patient Access Scheme	Restricted use: abiraterone acetate (Zytiga®) is accepted for restricted use within NHS Scotland with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. SMC restriction: abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen. Abiraterone plus prednisone was associated with significantly improved overall survival compared with placebo plus prednisone in patients with mCRPC previously treated with docetaxel. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Included on the Additional List, Specialist Use only for the indication in question.	October 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**
abiraterone acetate 250mg tablets (Zytiga®) *Janssen-Cilag Ltd* 12.10.15 *SMC Report No. 873/13* INDEPENDENT REVIEW PANEL Patient Access Scheme	Accepted: abiraterone acetate (Zytiga®) is accepted for use within NHS Scotland. Indication under review: abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. In a randomised, double-blind phase III study of adult men with chemotherapy-naive mCRPC, treatment with abiraterone acetate in combination with corticosteroid was associated with a statistically significant extended progression-free survival and overall survival when compared with placebo plus corticosteroid. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone acetate. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2015
afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®) *Boehringer Ingelheim International GmbH* 10.03.14 *SMC Report No 920/13* Patient Access Scheme	Accepted for use: afatinib (Giotrif®) is accepted for use within NHS Scotland as monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). In two phase III studies, in patients with EGFR mutation positive adenocarcinoma of the lung, afatinib was significantly superior to the chemotherapy regimen comparators for the primary endpoint of progression free survival. Overall survival data are immature. A mixed treatment comparison provides indirect comparative data versus other tyrosine kinase inhibitors. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of afatinib. 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.	For patients with a specific EGFR mutation, exon 19 deletion: Included on the Additional List, Specialist Use only for the indication in question. For all other indications: Not included on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is erlotinib.	October 2014 February 2014
afatinib (Giotrif ®) 20 mg/30 mg/40 mg/50 mg film-coated tablets *Boehringer Ingelheim Limited* 11.07.16 *SMC Report No 1174/16* NON SUBMISSION	NOT RECOMMENDED: afatinib (Giotrif®) is not recommended for use within NHS Scotland as monotherapy for the treatment of locally advanced or metastatic non small cell lung cancer of squamous histology progressing on or after platinum-based chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®) *Sanofi* 10.03.14 *SMC Report No 878/13* RESUBMISSION Patient Access Scheme	Accepted for use: aflibercept (Zaltrap®) is accepted for use within NHS Scotland in combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen. In one randomised, double-blind, phase III study, aflibercept plus FOLFIRI chemotherapy regimen resulted in statistically significant longer overall survival compared with placebo plus FOLFIRI chemotherapy regimen. However the effect was of relatively modest clinical benefit. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2014
alectinib hydrochloride (Alecensa®) 150mg hard capsules *Roche Products Ltd* 08.05.17 *SMC Report No 1257/17* NON SUBMISSION	As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib.	Not routinely available as not recommended for use in NHSScotland.	May 2017
alemtuzumab, 30mg/mL for concentrate for solution for infusion (MabCampath®) *Bayer plc, Bayer Schering Pharma Division* 08.09.08 *SMC Report No. 494/08*	Restricted use: alemtuzumab (MabCampath®) is accepted for restricted use within NHS Scotland for treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate It is restricted to use in patients with previously untreated B-CLL, with the cytogenetic abnormality 17p-deletion. Compared with an alkylating agent, alemtuzumab was associated with improved progression-free survival in patients with B-CLL. Data in patients with 17p-deletion are limited; improved survival was demonstrated in a sub-group analysis in 21 patients. 	Added to the Additional List for Specialist use only. It has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	May 2011
alemtuzumab (MabCampath®) Genzyme	Immunosupression for islet cell transplant recipients 	Added to the Additional List, for Specialist Use only. Alemtuzumab for immunosuppression for islet cell transplant recipients has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	January 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
alemtuzumab (MabCampath®) Genzyme	Treatment of relapsed chronic lymphocytic leukaemia (subcutaneous administration) 	Added to the Additional List, for Specialist Use only. Alemtuzumab for the treatment of relapsed chronic lymphocytic leukaemia has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	April 2012
anakinra (Kineret®) 100mg solution for injection in a pre-filled syringe *Swedish Orphan Biovitrum Ltd* 07.12.15 *SMC Report No.1116/15* NON SUBMISSION	NOT RECOMMENDED: anakinra (Kineret®) is not recommended for use within NHS Scotland. Indication under review: Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above, including: • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Muckle-Wells Syndrome (MWS) Familial Cold Autoinflammatory Syndrome (FCAS) 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	
anastrazole 1mg tablets (Arimidex®) *AstraZeneca UK Ltd* 12.09.05 *SMC Report No. 198/05*	Restricted use: anastrozole (Arimidex®) is accepted for restricted use within NHS Scotland in the adjuvant treatment of postmenopausal women with hormone receptor-positive early invasive breast cancer. Anastrozole has shown benefit over standard anti-oestrogen therapy in terms of disease-free survival in this patient group. It offers an alternative to tamoxifen and has a different adverse effects profile. Treatment with anastrozole should be initiated by a breast cancer specialist.	Added to LJF as second choice treatment for patients at risk of early recurrence or with contraindication to tamoxifen.	August 2010
anastrozole 1mg tablet (Arimidex®) *AstraZeneca UK Limited* 13.11.06 *SMC Report No. 322/06*	Restricted use: anastrozole (Arimidex®) is accepted for restricted use within NHS Scotland for the adjuvant treatment of early breast cancer in hormone receptor positive postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen. In a combined analysis of two trials, switching to anastrozole after 2 years of tamoxifen therapy rather than continuing with tamoxifen resulted in a 3.1% increase in event-free survival at three years follow-up. It offers an alternative to tamoxifen after initial adjuvant treatment with tamoxifen for 2-3 years and has a different adverse effects profile. Treatment with anastrozole is restricted to initiation by a breast cancer specialist.	'Not preferred' in Lothian as suitable alternatives exist. Note; this relates to this indication only.	August 2010

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
aprepitant (Emend®) *Merck, Sharpe & Dohme* 08.11.04 *SMC Report No. 132/04*	Restricted use: aprepitant (Emend®) is accepted for restricted use within NHS Scotland for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy. The antiemetic regimen incorporating aprepitant was superior to one regimen (where dexamethasone alone was used in the delayed phase of treatment), for the prevention of cisplatin-induced nausea and vomiting in the acute and delayed phases. It should be initiated only by appropriate hospital based specialists.	Added to the Additional List, for Specialist Use only.	July 2008
aprepitant 80mg, 125mg hard capsules (Emend®) *Merck Sharp and Dohme Ltd* 07.11.11 *SMC Report No. 242/06* RESUBMISSION	NOT RECOMMENDED: aprepitant (Emend®) as part of combination therapy is not recommended for use within NHS Scotland for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. Compared with a control regimen, aprepitant has been shown to increase the proportion of patients achieving a complete response in a study of breast cancer patients or experiencing no vomiting in patients with a range of tumour types, when patients were initiated on their first cycle of a moderately emetogenic chemotherapy regimen. However the control regimen was considered suboptimal for the treatment of delayed symptoms and evidence for use in subsequent cycles is limited. Overall the submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	NOT RECOMMENDED	
aprepitant, 80mg, 125mg hard capsules and 125mg powder for oral suspension (Emend®) *Merck, Sharpe & Dohme* 12.06.17 *SMC Report No. 1241/17*	As part of combination therapy, for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in infants, toddlers and children from the age of six months to less than 12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules).	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 2017
aprepitant (Emend®) 80mg,125mg hard capsules aprepitant (Emend®) 125mg powder for oral suspension *Merck Sharp & Dohme Limited* 10.07.17 *SMC Report No. 1252/17* PRODUCT UPDATE (abbreviated submission)	As part of combination therapy, for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy in children, toddlers and infants from the age of six months to <12 years (powder for oral suspension) and adolescents from the age of 12 years to 17 years (hard capsules).	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 2017
axitinib (Inlyta®) *Pfizer*	As a second-line treatment for advanced/metastatic renal carcinoma after pazaponib therapy. 	Added to the Additional List, for Specialist Use only. Axitinib as a second-line treatment for advanced/metastatic renal carcinoma after pazopanib therapy has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	April 2014

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
axitinib, 1mg and 5mg, film-coated tablets (Inlyta®) *Pfizer* 11.11.13 *SMC Report No. 855/13* RESUBMISSION Patient Access Scheme	Accepted for use: axitinib (Inlyta®) is accepted for use within NHS Scotland for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. In a phase III, open-label study, axitinib improved progression-free survival significantly more than another targeted therapy when used after first-line sunitinib or a cytokine. There was no significant improvement in overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of axitinib. 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. Additional tablet strengths are now available. 1mg, 3mg, 5mg and 7mg tablets are all included in the Patient Access Scheme.	December 2013 August 2015
azacitidine 100mg powder for suspension for injection (Vidaza®) *Celgene Ltd* 12.09.11 *SMC Report No. 589/09* RESUBMISSION Patient Access Scheme	Accepted for use: azacitidine (Vidaza®) is accepted for use within NHS Scotland for treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with intermediate-2 and high-risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML). Azacitidine therapy produced a significant increase in overall survival compared with conventional care regimens in previously untreated higher-risk MDS patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of azacitidine. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only.	November 2011
azacitidine (Vidaza®) 25 mg/mL powder for suspension for injection *Celgene Ltd* 11.07.16 *SMC Report No: 1175/16* NON SUBMISSION	NOT RECOMMENDED: azacitidine (Vidaza®) is not recommended for use within NHS Scotland for the reatment of adult patients aged 65 years or older who are not eligible for haematopoietic stem cell transplantation (HSCT) with acute myeloid leukaemia (AML) with >30% marrow blasts according to the World Health Organisation (WHO) classification. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
basiliximab (Simulect®) *Novartis*	For prevention of acute organ rejection in liver transplant in patients with or at risk of renal dysfunction to allow delayed introduction of calcineurin inhibitors, in order to reduce incidence of acute renal inpairment. 	Not recommended for use in Lothian. Basiliximab (Simulect®) has been categorised **BLACK** under the ADTC 'Policy and procedures for the use of unlicensed medicines', for the prevention of acute organ rejection in liver transplant	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**
belatacept powder for concentrate for solution for infusion 250mg vial and disposable syringe (Nulojix®) *Bristol Myers Squibb Pharmaceuticals Ltd* 11.06.12 *SMC Report No. 786/12*	NOT RECOMMENDED: belatacept (Nulojix®) is not recommended for use within NHS Scotland in combination with corticosteroids and mycophenolic acid, is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin-2 receptor antagonist for induction therapy to this belatacept-based regimen. Results of two phase III studies have demonstrated comparable graft and patient survival of belatacept versus a calcineurin inhibitor when used as part of a maintenance immunosuppressive regimen. Indirect efficacy data from a mixed treatment comparison are available for belatacept versus another calcineurin inhibitor, considered the key comparator in NHS Scotland. The submitting company's justification for 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 case to gain acceptance by SMC.	NOT RECOMMENDED	
belimumab, 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) *GlaxoSmithKline* 08.05.17 *SMC Report No. 775/12* RESUBMISSION Patient Access Scheme	Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	August 2017
bendamustine hydrochloride 25mg, 100mg powder for solution for infusion (Levact®) *Napp Pharmaceuticals Limited* 11.04.11 *SMC Report No. 694/11*	Accepted for use; bendamustine hydrochloride (Levact®) is accepted for use within NHS Scotland. Indication under review: first-line treatment of chronic lymphocytic leukaemia (CLL) (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate. Bendamustine showed significantly improved response rates and progression free survival when compared with another alkylating agent in patients with previously untreated advanced CLL, although the patients studied may have been younger and fitter than those eligible to receive bendamustine in Scottish clinical practice.	Added to the Additional List. Included on the Lothian Joint Formulary for the indication in question. Until further evidence is provided, the use of bendamustine in combination with rituximab can be undertaken via non-formulary route.	April 2012
bendamustine 2.5mg/mL powder for concentrate for solution for infusion (Levact®) *Napp Pharmaceuticals Limited* 11.04.11 *SMC Report No: 700/11* NON SUBMISSION	NOT RECOMMENDED: bendamustine (Levact ®) is not recommended for use within NHS Scotland. Indication under review: for the front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment. 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	

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bendamustine 2.5mg/mL powder for concentrate for solution for infusion (Levact®) *Napp Pharmaceuticals Limited* 11.04.11 *SMC Report No: 701/11* NON SUBMISSION	NOT RECOMMENDED: bendamustine (Levact ®) is not recommended for use within NHS Scotland. Indication under review: for the front line treatment of indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen. 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	
bendamustine (Levact®) *NAPP*	In combination with rituximab for relapsed chronic lymphocytic leukaemia. 	Added to the Additional List, for Specialist Use only. Bendamustine has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	February 2014
bendamustine 2.5mg/mL powder for concentrate for solution of rinfusion vials (Levact®) (available as 25mg and 100mg vials) *Napp Pharmaceuticals* Local formulary process	Relapsed and refractory multiple myeloma. 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2017
bevacizumab 100mg/4mL and 400mg/16mL solution for intravenous infusion (Avastin®) *Roche* 12.06.06 *SMC Report No. 221/05* RESUBMISSION Superseded by MTA 242 January 2012	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with intravenous fluorouracil/folinic acid or intravenous fluorouracil/folinic acid/irinotecan for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Bevacizumab, in combination with standard regimens containing fluorouracil and folinic acid or fluorouracil, folinic acid and irinotecan, improved overall and disease-free survival times compared to these standard regimens. However, the economic case has not been demonstrated. MTA 242 Bevacizumab in combination with non-oxaliplatin (fluoropyrimide-based) chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.	NOT RECOMMENDED	
bevacizumab (Avastin®) *Roche Pharmaceuticals* 09.07.07 *SMC Report No. 387/07* NON SUBMISSION	NOT RECOMMENDED: bevacizumab (Avastin®) in combination with paclitaxel is not recommended for first-line treatment of patients with metastatic breast cancer. 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**
bevacizumab (Avastin®) *Roche Pharmaceuticals* 10.12.07 *SMC Report No. 425/07* NON SUBMISSION	NOT RECOMMENDED: bevacizumab (Avastin®) in addition to platinum-based chemotherapy, is not recommended for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology. 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	
bevacizumab (Avastin®) *Roche Pharmaceuticals* 10.03.08 *SMC Report No. 459/08* NON SUBMISSION	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with interferon alfa-2a for the first line treatment of patients with advanced and/or metastatic renal cell cancer. 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	
bevacizumab, 100mg and 400mg vials (Avastin®) *Roche* 09.06.08 *SMC Report No.469/08*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with fluoropyrimidine-based chemotherapy for treatment of patients with metastatic carcinoma of the colon or rectum. In a randomised trial standard chemotherapy plus bevacizumab showed a small benefit over standard chemotherapy alone in terms of progression-free survival. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) *Roche Products Ltd.* 14.05.12 *SMC Report No.778/12*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with capecitabine is indicated for first-line treatment of patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. In a double-blind, multicentre, randomised, placebo-controlled phase III study in patients with locally recurrent or metastatic breast cancer, treatment with bevacizumab plus capecitabine was associated with an extended median progression-free survival of 2.9 months compared with capecitabine monotherapy. However, there was no overall significant improvement in survival. The submitting company did not present a sufficiently robust economic analysis and, in addition, their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by the SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) *Roche Products Ltd* 09.11.15 *SMC Report No.* *806/12* 2nd RESUBMISSION	Restricted: bevacizumab (Avastin®) is accepted for restricted use within NHS Scotland. Indication under review: In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. SMC restriction: In patients with FIGO stage IV disease Addition of bevacizumab to standard chemotherapy with carboplatin and paclitaxel increased progression-free survival. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the additional list, classified as **RED**, Specialist use only, under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian', for the indication in question. Off label dose being used.	April 2016
bevacizumab, 25mg/mL, concentrate for solution for infusion (Avastin®) *Roche Products Ltd* 11.03.13 *SMC Report No.* *853/13*	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelian ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents. A randomised double-blind, placebo-controlled, phase III study demonstrated a significant improvement in progression-free survival (PFS) in patients with platinum-sensitive recurrent ovarian cancer (ROC) treated with bevacizumab in combination with gemcitabine and carboplatin, compared with gemcitabine and carboplatin alone. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bevacizumab 25mg/mL concentrate for solution for infusion, (Avastin®) *Roche Products Ltd* 07.09.15 *SMC Report No. 1063/15* Patient Access Scheme	Restricted: bevacizumab (Avastin®) is accepted for restricted use within NHS Scotland. Indication under review: in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents. SMC restriction: to use in combination with paclitaxel. The addition of bevacizumab to chemotherapy improved progression free survival in patients with platinum-resistant ovarian cancer in an open-label phase III randomised study. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bevacizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2015
bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) *Roche Products Ltd* 09.05.16 *SMC Report No. 1135/16* Patient Access Scheme	Restricted: bevacizumab (Avastin®) is accepted for restricted use within NHS Scotland. Indication under review: in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. Restriction: for use in combination with cisplatin and paclitaxel. In an open-label, randomised, phase III study, the addition of bevacizumab to combination chemotherapy increased overall survival. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of bevacizumab. 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. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only, for the indication in question.	August 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bevacizumab (Avastin®) 25 mg/ml concentrate for solution for infusion *Roche Products Ltd* 12.09.16 *SMC Report No. 1190/16* NON SUBMISSION	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland in combination with erlotinib for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. 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	
bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) *Roche Products Ltd* 11.09.17 SMC No 1275/17 NON SUBMISSION	NOT RECOMMENDED: bevacizumab (Avastin®) is not recommended for use within NHS Scotland. Indication under review: In combination with carboplatin and paclitaxel for the treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED:	
bexarotene capsules (Targretin®) *Elan Pharma* 08.11.02 *SMC Report No. 14/02*	Restricted use: bexarotene capsules (Targretin®) is recommended as a second line treatment for patients with advanced (stages IIb or III) cutaneous T-cell lymphoma. Bexarotene treatment should normally be initiated and supervised by haematologists, dermatologists or oncologists and used for patients who have proved refractory both to local skin directed therapy and to at least one systemic treatment.	Added to the Additional List as a second line treatment for patients with cutaneous T-cell lymphoma (stages IIb or III).	May 2003
blinatumomab, 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®) *Amgen Europe B.V.* 13.06.16 *SMC Report No. 1145/16* Patient Access Scheme	Accepted for use: blinatumomab (Blincyto®) is accepted for use within NHS Scotland for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). In a non-comparative phase II study of patients with relapsed or refractory Philadelphia chromosome-negative B-precursor ALL, blinatumomab was associated with clinically relevant complete remission rates. Controlled data with clinical outcomes are currently lacking. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of blinatumomab. 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

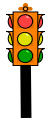
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bortezomib (Velcade®) *Ortho Biotech* 11.10.04 *SMC Report No. 126/04*	Accepted for use: bortezomib (Velcade®) is accepted for use within NHS Scotland for the treatment of patients with multiple myeloma who have received at least two prior therapies, have demonstrated disease progression on the last therapy and who are refractory to alternative licensed treatments for this stage of the disease. Bortezomib produced a disease response in approximately one third of these patients in an open-label uncontrolled study. Any other use of bortezomib should only take place within the context of a controlled study. The manufacturers are encouraged to mount an observational study in collaboration with haemato-oncologists to gain more information on the benefits and risks of this therapy.	Added to the Additional List, for Specialist use only. Bortezomib may be appropriate for patients who have relapsed after thalidomide treatment according to agreed protocol.	November 2004
bortezomib 3.5mg powder for intravenous injection (Velcade®) *Ortho Biotech* 09.11.09 *SMC Report No. 302/06* 2ND RESUBMISSION Patient Access Scheme	Accepted for use: bortezomib (Velcade®) is accepted for use within NHS Scotland as mono-therapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation. Bortezomib, compared to high dose dexamethasone, prolonged time to disease progression and improved survival in patients who had progressive multiple myeloma despite previous treatment with one to three lines of therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bortezomib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist use only.	December 2011
bortezomib (Velcade®) 3.5mg powder for subcutaneous injection *Janssen-Cilag Ltd* 10.12.12 *SMC Report No. 822/12* PRODUCT UPDATE (abbreviated submission) Patient Access Scheme	Accepted for use: bortezomib subcutaneous injection (Velcade®) is accepted for use within NHS Scotland in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant. As monotherapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation. The subcutaneous formulation of bortezomib has been shown to be clinically non-inferior to the intravenous formulation and is the same price. SMC previously accepted bortezomib intravenous injection as monotherapy in the treatment of multiple myeloma when the benefits of a Patient Access Scheme (PAS) were taken into account. The Patient Access Scheme Assessment Group (PASAG) has confirmed that this response-based PAS also applies to the subcutaneous formulation when used in this setting. This SMC advice is therefore contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. Bortezomib intravenous injection has also been accepted for use in NHS Scotland in specific circumstances in the first line treatment of multiple myeloma as Healthcare Improvement Scotland has endorsed NICE MTA No 228 (Bortezomib and thalidomide for the first line treatment of multiple myeloma) in July 2011. The PAS does not apply to the use of bortezomib in this setting.	Included on the Additional List, for Specialist Use only, for the indication included in PAS.	December 2012

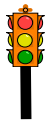
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bortezomib 3.5mg powder for solution for injection (Velcade®) *Janssen-Cilag Ltd* 13.01.14 *SMC Report No. 927/13*	Restricted use: bortezomib (Velcade®) is accepted for restricted use within NHS Scotland in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation. SMC restriction: use as triple therapy in combination with dexamethasone and thalidomide. Bortezomib, used in combination with dexamethasone and thalidomide for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation improved response rates compared with a dual combination regimen.	Included on the Additional List, for Specialist Use only, for the indication in question.	February 2014
bortezomib 3.5mg powder for solution for injection (Velcade®) *Janssen-Cilag Ltd* 07.09.15 *SMC Report No. 1075/15*	Accepted: bortezomib (Velcade®) is accepted for use within NHS Scotland. Indication under review: in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation. Bortezomib in combination with rituximab, cyclophosphamide, doxorubicin and prednisone significantly improved progression-free survival compared to a regimen containing rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone in adults with previously untreated mantle cell lymphoma who were unsuitable for haematopoietic stem cell transplantation	Included on the additional list, specialist use, for the indication in question.	October 2015
bosutinib 100mg, 500mg film-coated tablets (Bosulif®) *Pfizer Ltd* 09.02.15 *SMC Report No. 910/13* RESUBMISSION Patient Access Scheme	Accepted for use: bosutinib (Bosulif®) is accepted for use within NHS Scotland for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options. Major cytogenetic response was achieved in 23/52 patients who represented “unmet medical need” within a non-comparative phase I/II study, in which the full population included 546 patients with CP, AP or BP imatinib pre-treated Ph+ CML. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bosutinib. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 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**
brentuximab vedotin (Adcetris®) 50mg powder for concentrate for solution for infusion *Takeda UK Ltd* 13.10.14 *SMC Report No. 845/12*	Restricted use: brentuximab vedotin (Adcetris®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). SMC restriction: treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL): 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option In an open-label, single-arm study, patients with relapsed or refractory Hodgkin lymphoma treated with brentuximab vedotin achieved an objective response rate of 75%. Controlled data with clinical outcomes are currently lacking. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. Brentuximab is also indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). SMC cannot recommend use in sALCL as the company did did not include evidence for use in this indication in its submission.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2014
busulfan, 6mg/mL, intravenous (Busilvex®) *Pierre Fabre Ltd* 15.01.07 *SMC Report No. 337/06*	Accepted for use: busulfan for intravenous infusion (Busilvex®) is accepted for use within NHS Scotland as part of a combination regimen for conditioning treatment prior to conventional haematopoietic progenitor cell transplantation (HPCT) in paediatric and adult patients. The intravenous preparation offers advantages to patients over the oral formulation in terms of convenience of administration and predictability of blood levels. In adults it should be followed by cyclophosphamide (BuCy2) and in children it should be followed by cyclophosphamide (BuCy4) or by melphalan (BuMel).	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	June 2008

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
cabazitaxel, 60mg concentrate and solvent for solution for infusion (Jevtana®) *Sanofi* 12.12.16 *SMC Report No. 735/11* 2nd RESUBMISSION Patient Access Scheme	Restricted use: cabazitaxel (Jevtana®) is accepted for restricted use within NHS Scotland in combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. SMC restriction: for use in patients who have received at least 225mg/m^2 (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. In an open-label, multicentre, randomised-controlled, phase III study in patients with metastatic hormone refractory prostate cancer, treatment with cabazitaxel plus prednisone/prednisolone was associated with an extended median overall survival of 2.4 months compared with an alternative chemotherapy regimen. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cabazitaxel. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	April 2017
cabozantinib 20mg and 80mg hard capsules (Cometriq®) *Swedish Orphan Biovitrum Ltd.* 09.03.15 *SMC Report No. 1022/15*	NOT RECOMMENDED: cabozantinib 20mg and 80mg hard capsules (Cometriq®) is not recommended for use within NHS Scotland for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma. In one pivotal, phase III study, cabozantinib was associated with a significant advantage in progression-free survival over placebo. However, the difference between cabozantinib and placebo did not reach statistical significance in the subgroup of patients with Rearranged during Transfection (RET) negative tumours. The summary of product characteristics therefore notes that for patients in whom RET mutation status is unknown or is negative, a possible lower benefit should be taken into account before individual treatment decision. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	March 2015
cabozantinib 20mg, 40mg and 60mg film-coated tablets (Cabometyx®) *Ipsen Ltd.* 12.06.17 *SMC Report No. 1234/17* Patient Access Scheme	For the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	August 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
canakinumab (Ilaris®) 150 mg/mL, powder for solution for injection intended *Novartis Pharmaceuticals* 08.11.10 *SMC Report No. 658/10* NON SUBMISSION	NOT RECOMMENDED: canakinumab (Ilaris®) 150 mg/mL, powder for solution for injection intended is not recommended for use within NHSScotland. Indication under review: Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result SMC cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
canakinumab (Ilaris®) 150 mg powder for solution for injection *Novartis Pharmaceuticals Ltd* 10.06.13 *SMC Report No. 882/13* NON SUBMISSION	NOT RECOMMENDED**:** canakinumab (Ilaris®) is not recommended for use within NHS Scotland for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above including: • Muckle-Wells Syndrome (MWS) • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash 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	
capecitabine (Xeloda®) *Roche* 07.03.03 *SMC Report No. 34/03*	Restricted use: capecitabine (Xeloda®) is accepted for restricted use within NHS Scotland. Capecitabine is recommended for use in Scotland by oncologists with appropriate expertise in treating locally advanced/metastatic breast cancer. It is an orally active treatment which has improved outcomes both as monotherapy in those previously treated with an anthracycline and a taxane, and in combination with docetaxel in those previously treated with an anthracycline.	Included in the Formulary.	
capecitabine 150 and 500mg tablets (Xeloda®) *Roche* 05.08.05 *SMC Report No. 193/05*	Accepted for use: capecitabine (Xeloda®) is accepted for use within NHS Scotland for the adjuvant treatment of patients following surgery for Stage III (Dukes' C stage) colon cancer. Oral capecitabine appears to be as least as effective as standard IV 5FU/FA chemotherapy with the convenience of oral administration. It should only be prescribed by oncologists. It is more expensive than IV chemotherapy regimens. However, its use may allow changes to service delivery that have individual patient or organisational benefits.	Added to the Additional List, for Specialist Use only.	October 2005

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**
capecitabine, 150mg and 500mg tablets (Xeloda®) *Roche* 10.09.07 *SMC Report No. 401/07*	Accepted for use: capecitabine (Xeloda®) is accepted for use within NHS Scotland for first line treatment of patients with advanced gastric cancer in combination with a platinum-based chemotherapy regimen. Capecitabine was non-inferior to continuously infused intravenous 5-FU in terms of progression-free survival when each was used in combination with a platinum-based drug in patients with advanced gastric cancer. It also demonstrated non-inferiority in overall survival compared with continuously infused intravenous 5-FU in patients with advanced gastric cancer when each was used in a triple regimen containing a platinum-based drug and an anthracycline drug. Capecitabine is more expensive than 5-FU, however, the convenience of oral administration may allow changes to service delivery that have individual patient or organisational benefits.	Added to the Additional List, for Specialist Use only.	January 2009
capecitabine 150mg and 500mg tablets (Xeloda®) *Roche Products Limited* 13.10.08 *SMC Report No.507/08*	Accepted for use: capecitabine 150mg and 500mg tablets (Xeloda®) is accepted for use within NHS Scotland for the treatment of metastatic colorectal cancer. The convenience of oral administration may allow changes to service delivery that have individual patient or organisational benefits, though these may be lessened when it is used in regimens whose other components require intravenous administration.	Added to the Additional List – for Specialist Use only. Approved under ADTC unlicensed medicines policy in January 2005.	August 2009
capecitabine, 150mg, 500mg, tablets (Xeloda®) *Roche Products Limited* 08.08.11 *SMC Report No. 716/11*	Accepted for use: capecitabine (Xeloda®) is accepted for use within NHS Scotland. Indication under review: The adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer in combination with oxaliplatin. At 55 months, disease free survival was significantly increased for capecitabine plus oxaliplatin-treated patients compared with a recognised regimen containing a fluoropyramidine in the adjuvant treatment of patients with completely resected stage III (Dukes' C) colon cancer.	Added to the Additional List, for Specialist Use only.	August 2011
capecitabine (Xeloda®) *Roche*	Adjuvant use following potentially curative surgery for adenocarcinoma of the pancreas to replace 5FU/folinic acid given according to the Mayo schedule	Added to the LJF as first choice for use post-operatively in the treatment of adenocarcinoma of the pancreas, for Specialist Use only.	January 2007
capecitabine (Xeloda®) *Roche*	Colorectal cancer 	Added to the Additional List for use in secondary care only. Specialist use only. capecitabine (Xeloda®) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	January 2005

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**
capecitabine (Xeloda®) *Roche*	Pre-operative chemoradiation in patients with locally advanced rectal cancer requiring down staging prior to definitive resection or in patients with good performance status and low volume metastatic disease requiring durable palliation for unresectable rectal cancer 	Added to the Additional List, for Specialist Use only. capecitabine (Xeloda®) (for pre-operative chemoradiation in patients with locally advanced rectal cancer requiring down staging prior to definitive resection or in patients with good performance status and low volume metastatic disease requiring durable palliation for unresectable rectal cancer) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	September 2006
capecitabine (Xelox®) *Roche*	In combination with epirubicin and cisplatin (ECX) for palliative treatment of advanced oesphagogastric cancer 	Added to the Additional List. Capecitabine (Xelox®) in combination with epirubicin and cisplatin (ECX) for first line use as palliative treatment of advanced oesophagogastric cancer has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	September 2005
capecitabine/oxaliplatin (Xeloda®/Eloxatin®) *Roche*	First choice treatment for Dukes B colorectal cancer	Added to the Additional List for Specialist Use only.	July 2007
carmustine 7.7mg implant (Gliadel®) *Link Pharmaceuticals Ltd* 12.12.05 *SMC Report No. 215/05*	Accepted for use: carmustine implant (Gliadel®) is accepted for use within NHS Scotland for the treatment of newly diagnosed high-grade malignant glioma patients as an adjunct to surgery and radiation. In the pivotal study, the use of carmustine implants was associated with a 29% relative decrease in the risk of death, which equates to an increase in median survival time of 2.3 months.	Added to the Additional List, for Specialist Use only.	March 2006
catumaxomab (Removab®) 10 and 50 microgram concentrate for solution for infusion *Fresenius Biotech GmbH* 09.04.12 *SMC Report No. 788/12* NON SUBMISSION	NOT RECOMMENDED: catumaxomab (Removab®) is not recommended for use within NHS Scotland for intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. 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**
carfilzomib 60mg powder for solution for infusion (Kyprolis®) *Amgen Ltd.* 16.01.17 *SMC Report No. 1171/16* RESUBMISSION	NOT RECOMMENDED: carfilzomib (Kyprolis®) is not recommended for use within NHS Scotland in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Carfilzomib in combination with lenalidomide and dexamethasone improved progression free survival compared with lenalidomide and dexamethasone in adults with relapsed and / or refractory multiple myeloma who had received one to three prior therapies. 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 views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	
carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®) *Amgen Ltd.* 07.08.17 *SMC Report No. 1242/17* Patient Access Scheme	In combination with dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	Formulary classification not yet decided – waiting for information from clinicans.	
ceritinib 150mg hard capsules (Zykadia®) *Novartis Europharm Limited* 07.12.15 *SMC Report No. 1097/15* Patient Access Scheme	Accepted: ceritinib (Zykadia®) is accepted for use within NHS Scotland. Indication under review: Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib. In two non-comparative studies (one phase I and one phase II) of patients with advanced ALK-positive NSCLC previously treated with crizotinib, treatment with ceritinib was associated with clinically meaningful tumour responses and median overall survival of approximately 15 to 17 months. Controlled data with clinical outcomes are currently lacking. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ceritinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the additional list, Specialist use only, for the indication in question.	April 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**
cetuximab 100mg in 50mL solution for infusion (Erbitux®) *Merck Pharmaceuticals Ltd* 10.10.05 *SMC Report No. 155/05* FOLLOWING INDEPENDENT REVIEW PANEL ASSESSMENT Superseded by MTA 242 January 2012	NOT RECOMMENDED: cetuximab (Erbitux®) is not recommended for use within NHS Scotland in combination with irinotecan for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy. MTA 242 Cetuximab monotherapy or combination chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.	NOT RECOMMENDED	
cetuximab 2mg/mL intravenous infusion (Erbitux®) *MerckKGaA* 10.07.06 *SMC Report No. 279/06*	Restricted use: cetuximab (Erbitux®) is accepted for restricted use within NHS Scotland in combination with radiation therapy for the treatment of patients with locally advanced squamous cell cancer of the head and neck. It is restricted to patients who are not appropriate for or unable to tolerate chemo-radiotherapy and who are of good performance status with no evidence of distant metastases. It is also restricted to use by specialists in the management of head and neck cancer.	Added to the Additional List, for Specialist Use only.	September 2006
cetuximab 5mg/mL solution for infusion (Erbitux®) *Merck Serono* 09.03.09 *SMC Report No. 547/09* NON SUBMISSION	NOT RECOMMENDED: cetuximab (Erbitux®) is not recommended for use within NHS Scotland for the treatment of patients with squamous cell cancer of the head and neck in combination with platinum-based chemotherapy for recurrent and/or metastatic disease. 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	
cetuximab, 100mg/20mL and 500mg/100mL solution for intravenous infusion (Erbitux®) *Merck Serono Ltd* 08.02.10 *SMC Report No. 543/09* RESUBMISSION Patient Access Scheme	Restricted use: cetuximab (Erbitux®) is accepted for restricted use within NHS Scotland for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, Kirsten rat sarcoma (KRAS) wild-type metastatic colorectal cancer in combination with chemotherapy. Post hoc analyses from one phase III and one phase II study in patients with KRAS wild-type status who had not previously received chemotherapy for metastatic disease, showed an increase in overall response rate and a small, but statistically significant, increase in median progression free survival time, when cetuximab was added to standard first-line combination chemotherapy. Cetuximab is restricted to use in patients who have not previously received chemotherapy for their metastatic disease, with liver metastases only that are considered non-resectable but in whom potentially curative liver metastasis resection would be undertaken if the lesions became resectable after treatment with chemotherapy and cetuximab. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cetuximab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist use only.	August 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
cetuximab, 100mg/20mL and 500mg/100mL solution for infusion (Erbitux®) *Merck Serono Ltd.* 12.01.15 *SMC Report No. 1012/14* Patient Access Scheme	Restricted use: cetuximab (Erbitux®) is accepted for restricted use within NHS Scotland for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer: • in combination with irinotecan-based chemotherapy • in first-line in combination with FOLFOX • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. SMC restriction: for use in patients with RAS wild-type metastatic colorectal cancer, in combination with irinotecan or oxaliplatin-based chemotherapy, in patients who have not previously received chemotherapy for their metastatic disease (first-line treatment). Efficacy data for the RAS wild-type population come from post hoc subgroup analyses of two studies that compared cetuximab plus chemotherapy with chemotherapy alone. In the RAS wild-type population, response rates (complete and partial responses) were significantly higher in both studies and overall survival was significantly longer in one study for cetuximab plus chemotherapy than chemotherapy alone. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of cetuximab. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist use only.	May 2015
cinacalcet 30, 60 and 90 mg film-coated tablets (Mimpara®) *Amgen Ltd* 08.05.06 *SMC Report No. 271/06* NON SUBMISSION	NOT RECOMMENDED: cinacalcet (Mimpara®) is not recommended for use within NHSScotland for the reduction of hypercalcaemia in patients with parathyroid carcinoma. 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	
cisplatin/ vinorelbine	Adjuvant non-small cell lung cancer	Added to the Additional List, for Specialist Use only.	October 2005
cladribine 2mg/mL solution for injection (LITAK®) *Lipomed GmbH* 09.03.09 *SMC Report No. 537/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: cladribine (Litak®) is accepted for use in NHS Scotland for the treatment of hairy cell leukaemia. In patients for whom cladribine is an appropriate agent for this indication, the 2mg/mL solution allows administration by subcutaneous bolus injection over five consecutive days rather than by continuous intravenous infusion of the existing 1mg/mL solution for seven consecutive days. This may confer advantages in terms of convenience to patients and service delivery at a lower cost per course.	New formulation of a product already included in the Additional List.	March 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**
clofarabine, 1mg/mL concentrate for solution for infusion (Evoltra®) *Bioenvision Limited* 15.01.07 *SMC Report No. 327/06*	Restricted use: clofarabine (Evoltra®) is accepted for restricted use within NHS Scotland for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients (= 21 years) who have relapsed or are refractory after receiving at least two prior regimens and where there is no other treatment option anticipated to result in a durable response. It is restricted to patients in whom clofarabine is being used as a treatment to bridge to HSCT and restricted to use by specialists in paediatric haemato-oncology. It is not cost effective when used for palliation.	Added to the Additional List, for Specialist Use only.	March 2009
cobimetinib (Cotellic®) 20mg film-coated tablets *Roche Products Ltd* 12.09.16 *SMC Report No. 1191/16* NON SUBMISSION	NOT RECOMMENDED: cobimetinib (Cotellic®) is not recommended for use within NHS Scotland in combination with vemurafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. 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	
crizotinib, 200mg and 250mg, hard capsule (Xalkori®) *Pfizer Ltd.* 07.10.13 *SMC Report No. 865/13* RESUBMISSION Patient Access Scheme	Accepted for use: crizotinib (Xalkori®) is accepted for use within NHS Scotland for the treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). In a phase III clinical study in patients with previously treated anaplastic lymphoma kinase (ALK)-positive advanced NSCLC, crizotinib significantly increased progression-free survival compared with standard chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. 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.	November 2013
crizotinib, 200mg and 250mg hard capsule (Xalkori®) *Pfizer Limited* 11.07.16 *SMC Report No. 1152/16* Patient Access Scheme	Accepted for use: crizotinib (Xalkori®) is accepted for use within NHS Scotland as first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). In patients with previously untreated advanced ALK-positive NSCLC, crizotinib significantly improved progression-free survival compared with a standard systemic anti-cancer therapy. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. 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**
cytarabine 50mg liposomal suspension for injection (DepoCyte®) *Napp Pharmaceuticals* 09.05.05 SMC Report No. 164/05	NOT RECOMMENDED: cytarabine liposomal suspension for injection (DepoCyte®) is not recommended for use within NHS Scotland for the intrathecal treatment of lymphomatous meningitis. Intrathecally administered cytarabine liposomal suspension cleared malignant cells from the cerebrospinal fluid, however effects on symptom improvement were not well defined and the cost-effectiveness compared to cytarabine solution has not been demonstrated.	NOT RECOMMENDED	
dabrafenib, 50mg and 75mg hard capsules (Tafinlar®) *GlaxoSmithKline* 09.03.15 *SMC Report No. 1023/15* Patient Access Scheme	Restricted use: dabrafenib (Tafinlar®) is accepted for restricted use within NHS Scotland as monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. SMC restriction: for use in patients with unresectable or metastatic BRAFV600 mutation-positive metastatic melanoma who have received no prior therapy. In a phase III randomised open-label study, treatment with dabrafenib extended median progression free survival by 4.2 months compared with chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dabrafenib. It is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only, for the indication in question.	May 2015
daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®) *Biogen Idec Ltd.* 10.04.17 *SMC Report No. 1216/17* Patient Access Scheme	In adult patients for the treatment of relapsing forms of multiple sclerosis. Restriction: for use • in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or • in patients with RRMS with an inadequate response to disease modifying therapy	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines.	May 2017
dalteparin (Fragmin®) *Pharmacia*	Thromboprophylaxis in patients with oesophago-gastric cancer undergoing pre-operative cisplatin-based chemotherapy prior to surgery with curative intent. 	Added to the Additional List, for Specialist Use only. Dalteparin for thromboprophylaxis in patients with oesophago-gastric cancer undergoing pre-operative cisplatin-based chemotherapy prior to surgery with curative intent has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	December 2013

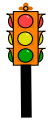
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) *Janssen-Cilag Ltd.* 16.01.17 *SMC Report No. 1205/17*	NOT RECOMMENDED: daratumumab (Darzalex®) is not recommended for use within NHS Scotland as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. In a pooled analysis of patients in a phase I/II and a phase II study, with heavily pre-treated multiple myeloma, who received the licensed dosing schedule of daratumumab, there was an overall response rate of 31%. The submitting company's justification of the treatment's costs in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic and clinical analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	
darbepoetin alfa (Aranesp®) *Amgen Ltd* 08.05.06 *SMC Report No. 273/06* NON SUBMISSION	NOT RECOMMENDED: darbepoetin alfa (Aranesp®) is not recommended for use within NHSScotland for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this formulation. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
darbepoetin alfa (Aranesp®) SureClick *Amgen Ltd* 08.05.06 *SMC Report No. 265/06* NON SUBMISSION	NOT RECOMMENDED: darbepoetin alfa (Aranesp®) SureClick is not recommended for use within NHS Scotland for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this formulation. As a result we cannot recommend its use within NHS Scotland.	NOT RECOMMENDED	
dasatinib, 20mg, 50mg, 70mg tablets (Sprycel®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 07.05.07 *SMC Report No. 370/07* *Superseded by MTA 241 January 2012*	Restricted use: dasatinib, 20mg, 50mg, 70mg tablets (Sprycel®) is accepted for restricted use within NHS Scotland for the treatment of adults with chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate. It should be restricted to use in patients who are in the chronic phase of the disease. The manufacturer's justification of the treatment's cost in relation to its health benefits for the accelerated or blast phases was not sufficient to gain acceptance by SMC. MTA 241 Dasatinib is not recommended for the treatment of chronic, accelerated or blast-crisis phase CML in adults with imatinib intolerance or whose CML is resistant to treatment with standard-dose imatinib.	Added to the Additional List, Specialist Use only, for the treatment of CML in patients intolerant to, or not responding to, imatinib. MTA 241 supersedes SMC advice and therefore supersedes FC decision. NOT RECOMMENDED	March 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**
dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 12.09.16 *SMC Report No. 370/07* RESUBMISSION Patient Access Scheme	Accepted for use: dasatinib (Sprycel®) is accepted for use within NHS Scotland for the treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate. In patients with chronic, accelerated or blast phase CML, dasatinib produced haematological and cytogenetic responses in two phase III dosing ranging studies. In a phase II study dasatinib was associated with higher haematological and cytogenetic responses relative to another tyrosine kinase inhibitor in patients with chronic phase CML. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dasatinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2016
dasatinib, 20mg, 50mg, 70mg tablets (Sprycel®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 07.05.07 *SMC Report No. 371/07*	NOT RECOMMENDED: dasatinib 20mg, 50mg, 70mg (Sprycel®) is not recommended for use within NHS Scotland for the treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia with resistance or intolerance to prior therapy. It has been associated with haematological and cytogenetic responses in patients resistant or intolerant to existing treatment. However, the economic case was not sufficiently robust and the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	
dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 12.09.16 *SMC Report No. 1170/16* Patient Access Scheme	Accepted for use: dasatinib (Sprycel®) is accepted for use within NHS Scotland for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase. In an open-label, phase III study, dasatinib was associated with significantly higher cytogenetic and molecular response rates at 12 months compared with another tyrosine kinase inhibitor. There were no differences in progression-free or overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dasatinib. 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, for Specialist Use only, for the indication in question.	December 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**
decitabine (Dacogen®) 50 mg powder for concentrate for solution for infusion *Janssen-Cilag Ltd* 14.01.13 *SMC Report No. 846/12* NON SUBMISSION	NOT RECOMMENDED: decitabine (Dacogen®) is not recommended for use within NHS Scotland for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy. 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	
defibrotide, 80mg/mL, concentrate for solution for infusion (Defitelio®) *Gentium GmbH* 09.06.14 *SMC Report No. 967/14* Patient Access Scheme	Accepted for use: defibrotide (Defitelio®) is accepted for use within NHS Scotland for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy. In a phase III open-label study, defibrotide was associated with improved complete response rate and survival in patients with severe VOD, compared with a historical control group. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of defibrotide. 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.	August2014
degarelix 120mg, 80mg powder and solvent for solution for injection (Firmagon®) *Ferring Pharmaceuticals Ltd* 17.01.11 *SMC Report No. 560/09* RESUBMISSION Patient Access Scheme	Accepted for use: degarelix (Firmagon®) is accepted for use within NHS Scotland. Degarelix is a gonadotropin-releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependent prostate cancer. In one study that included patients with all stages of prostate cancer, degarelix was shown to be non-inferior to a luteinising hormone releasing hormone (LHRH) agonist in suppressing testosterone levels over a one year treatment period without an initial testosterone flare. This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of degarelix. 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 and a prescribing note, for use in patients who are at risk of spinal cord compression.	August 2012
denosumab 60mg solution for injection in pre-filled syringe (Prolia®) *Amgen Ltd* 13.12.10 *SMC Report No. 670/10* NON SUBMISSION	NOT RECOMMENDED: denosumab (Prolia®) is not recommended for use within NHS Scotland. Indication under review: bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. 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**
denosumab 120 mg solution for injection (Xgeva®) *Amgen* October 2012 *NICE MTA 265* *Supersedes SMC Report No. 752/11*	Denosumab is recommended as an option for preventing skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from breast cancer and from solid tumours other than prostate if: • bisphosphonates would otherwise be prescribed and • the manufacturer provides denosumab with the discount agreed in the patient access scheme.	Included on the LJF, Specialist Use only, for the indication in question. Application was for breast cancer patients only.	April 2013
denosumab (Xgeva)®) 120mg solution for injection *Amgen Ltd* 07.12.15 *SMC Report No. 1119/15* NON SUBMISSION	NOT RECOMMENDED: denosumab (Xgeva®) is not recommended for use within NHS Scotland. Indication under review: Adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity 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	
dexamethasone 2mg and 4mg soluble tablets	To reduce the tablet burden in patients receiving large dexamethasone doses. Dexamethasone 500microgram non-soluble tablets, should remain on formulary as there is no soluble option for that strength.	Routinely available in line with national guidance. Included in the Lothian Joint Formulary.	August 2017
dexrazoxane (Cardioxane®) *Novartis Pharmaceuticals UK Ltd* 12.11.07 *SMC Report No. 419/07* NON SUBMISSION	NOT RECOMMENDED: dexrazoxane (Cardioxane®) is not recommended for use within NHSScotland for the prevention of chronic cumulative cardiotoxicity caused by doxorubicin or epirubicin use in advanced and/or metastatic cancer patients after previous anthracycline containing treatment. 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	
dexrazoxane 20mg/mL, for infusion (Savene®) *TopoTarget A/S* 13.10.08 *SMC Report No. 361/07* RESUBMISSION	NOT RECOMMENDED: dexrazoxane (Savene®) is not recommended for use within NHS Scotland for the treatment of anthracycline extravasation. Data from non-comparative, open-label phase II/III studies indicate that administration of dexrazoxane is associated with a relatively low rate of surgery and adverse sequelae following extravasation of anthracyclines. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC and in addition the justification of the treatment's cost in relation to its health benefits was not sufficient.	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**
docetaxel (Taxotere®) *Aventis* 09.05.03 *SMC Report No. 42/03*	Restricted use: docetaxel, in combination with cisplatin, is an effective treatment option for the first line treatment of unresectable, locally advanced or metastatic (stage III/IV) non-small cell lung cancer (NSCLC). In common with the other drugs recommended by Quality Improvement Scotland (QIS) for this condition, benefit has only been proven in patients with good performance status. Estimated cost per quality adjusted life year (QALY) gained is relatively high. Docetaxel should be initiated by respiratory physicians/oncologists experienced in the treatment of NSCLC.	Included in Formulary.	
docetaxel (Taxotere®) injection concentrate *Sanofi-Aventis UK* 13.11.06 *SMC Report No. 333/06* NON SUBMISSION	NOT RECOMMENDED: docetaxel (Taxotere®) injection concentrate in combination with cisplatin and 5-fluorouracil is not recommended for use within NHSScotland for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. 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	
docetaxel 20 and 80mg concentrate and solvent for solution for infusion (Taxotere®) *Sanofi-Aventis* 07.05.07 *SMC Report No. 369/07*	Restricted use: docetaxel (Taxotere®) is accepted for restricted use within NHS Scotland for the induction treatment of patients with unresectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil. It is restricted to patients in whom induction chemotherapy is appropriate. The docetaxel-containing induction regimen was associated with improved progression-free and overall survival, compared with cisplatin and 5-fluorouracil alone, in patients with good performance status.	Added to the Additional List, for Specialist Use only.	July 2007
docetaxel 20mg, 80mg concentrate and solvent for solution for infusion, single dose vials (Taxotere®) *Sanofi-Aventis* 10.10.05 *SMC Report No. 201/05*	Accepted for use: docetaxel (Taxotere®) is accepted for use within NHS Scotland in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of operable, node-positive breast cancer. Docetaxel in combination with doxorubicin and cyclophosphamide was associated with a significant improvement in disease free survival at 5 years when compared with one of the standard treatment regimens. However, this benefit is associated with an increased risk of toxicity. Docetaxel has demonstrated cost effectiveness in comparison to standard treatment regimen used in NHS Scotland.	Added to the Formulary, for Specialist Use only.	November 2005
docetaxel concentrate and solvent for solution for infusion, single dose vials (Taxotere®) *Sanofi-Aventis* 07.11.05 *SMC Report No. 209/05*	SMC - not recommended for use. NICE - recommends for use, within its licensed indications (NICE technology appraisal guidance 101. Docetaxel for the treatment of hormone-refractory metastatic prostate cancer. June 2006. www.nice.org.uk/page.aspx?o=TA101) NHS QIS www.nhshealthquality.org/nhsqis advises that this NICE appraisal supersedes the advice issued by the Scottish Medicines Consortium 7 November 2005.	Added to the LJF as first choice, for Specialist Use only.	January 2007

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
docetaxel 20 and 80mg concentrate and solvent for solution for infusion (Taxotere®) *Sanofi-aventis* 07.07.08 *SMC Report No 481/08*	Restricted use: accepted for restricted use within NHS Scotland for the induction treatment of patients with resectable locally advanced squamous cell carcinoma of the head and neck in combination with cisplatin and 5-fluorouracil. It is restricted to patients in whom induction chemotherapy is appropriate. In the pivotal study, which included patients with technically resectable disease, the docetaxel-containing induction regimen was associated with improved overall survival compared with cisplatin and 5-fluorouracil alone. SMC has previously issued advice for patients with unresectable disease and this now extends the advice to patients with resectable disease.	Added to the Additional List, Specialist Use only.	May 2009
docetaxel (Taxotere®) 20 mg/1ml and 80 mg/4ml and 160 mg/8ml concentrate for solution for infusion *Sanofi Aventis* 08.11.10 *SMC Report No. 659/10* NON SUBMISSION	NOT RECOMMENDED: docetaxel (Taxotere®) in combination with doxorubicin and cyclophosphamide is not recommended for use within NHS Scotland. Indication under review: adjuvant treatment of patients with operable node-negative breast cancer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result SMC cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
docetaxel	Treatment in patients with newly diagnosed (within 3 months of starting LHRH analogue or antagonist therapy) metastatic or locally advanced ($T_{any}N_1M_0$ or $T_{3-4}N_0M_0$) prostate cancer with a performance status of 0 -1 and no contraindication to chemotherapy (e.g. marrow failure). 	Added on the Additional List, specialist use only. Docetaxel has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	September 2015
elotuzumab (Empliciti®) 300mg and 400mg powder for concentrate for solution for infusion *Bristol Myers Squibb Pharmaceutical Limited* 08.08.16 *SMC Report No. 1183/16* NON SUBMISSION	NOT RECOMMENDED: elotuzumab (Empliciti®) is not recommended for use within NHS Scotland for the treatment of multiple myeloma in combination with lenalidomide and dexamethasone in adult patients who have received at least one prior 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	

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**
eltrombopag (Revolade®) film-coated tablets 25mg and 50mg *Novartis UK Ltd* 16.01.17 *SMC Report No. 1206/17* Patient Access Scheme PRODUCT UPDATE (abbreviated submission)	Restricted use: eltrombopag (Revolade®) is accepted for restricted use within NHS Scotland for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year to 17 years who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). SMC restriction: use in patients with severe symptomatic ITP or a high risk of bleeding. Eltrombopag has previously been accepted for restricted use in adult patients with chronic immune (idiopathic) thrombocytopenic purpura. The license has been extended to include children from 1 year. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eltrombopag. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, for Specialist Use only, for the indication in question.	January 2017
enzalutamide 40mg soft capsules (Xtandi®) *Astellas Pharma Ltd* 11.11.13 *SMC Report No. 911/13* Patient Access Scheme	Accepted for use: enzalutamide (Xtandi®) is accepted for use within NHS Scotland for the treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy. In one randomised, double-blind, phase III clinical study, enzalutamide significantly increased overall survival compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of enzalutamide. 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.	December 2013
enzalutamide, 40mg soft capsules (Xtandi®) *Astellas Pharma Ltd.* 07.03.16 *SMC Report No. 1066/15* INDEPENDENT REVIEW PANEL Patient Access Scheme	Accpeted use: enzalutamide (Xtandi®) is accepted for use within NHS Scotland. Indication under review: Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. In a randomised, double-blind phase III study of adult men with chemotherapy naive mCRPC treatment with enzalutamide was associated with a statistically significant extended overall survival and radiographic progression free survival compared to placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of enzalutamide. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the additional list, Specialist use only, for the indication in question.	April 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**
epirubicin (Pharmorubicin®), cisplatin (Platinex®) and capecitabine (Xeloda®) (ECX) *Pharmacia, Bristol-Myers Squibb, Roche*	Peri-operative treatment of operable gastric and type 3 oesophagogastric junctional adenocarcinomas.	Added to the LJF as first choice treatment for peri-operative treatment of operable gastric and type 3 oesophagogastric junctional adenocarcinomas, Specialist Use only.	September 2007
eribulin 0.44mg/mL solution for injection (Halaven®) *Eisai Ltd.* 10.10.11 *SMC Report No. 726/11* Superseded by SMC No. 1065/15	NOT RECOMMENDED: eribulin (Halaven®) is not recommended for use within NHS Scotland. eribulin monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments. In a randomised, phase III, open-label study eribulin-treated patients had 2.5 months additional survival compared to the comparator, treatment of physicians choice, which included a range of single agent chemotherapy treatments. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	Superseded by SMC No. 1065/15 See below	
eribulin (mesilate), 0.44mg/mL, solution for injection (Halaven®) *Eisai Ltd.* 07.03.16 *SMC Report No. 1065/15* RESUBMISSION Patient Access Scheme	Restricted use: eribulin (Halaven®) is accepted for restricted use within NHS Scotland. Indication under review: for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. SMC restriction: for use in patients with locally-advanced or metastatic breast cancer who have progressive disease after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine if indicated. In a randomised, phase III, open-label study, median overall survival was extended by 2.5 months in patients treated with eribulin compared with the comparator, treatment of physician's choice, which included a range of single agent chemotherapy treatments. In the subgroup of patients previously treated with capecitabine the extension to median overall survival was 2.9 months. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eribulin. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. This supersedes previous advice for eribulin (SMC No. 726/11).	Included on the Additional List, for Specialist Use only, for the indication 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**
erlotinib (Tarceva®) *Roche Pharmaceuticals* 09.07.07 *SMC Report No. 382/07* NON SUBMISSION	NOT RECOMMENDED: erlotinib (Tarceva®) in combination with gemcitabine is not recommended for use within NHSScotland for the treatment of patients with metastatic pancreatic cancer. 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	
erlotinib, 100 and 150mg film-coated tablets (Tarceva®) *Roche* 12.06.06 *SMC Report No. 220/05* RESUBMISSION SMC advice superseded by NICE MTA383, February 2016 Patient Access Scheme	NICE MTA374 states: erlotinib is recommended as an option for treating locally advanced or metastatic non-small-cell lung cancer that has progressed in people who have had non-targeted chemotherapy because of delayed confirmation that their tumour is epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation-positive, only if the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE technology appraisal guidance 258. Erlotinib is recommended as an option for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours of unknown EGFR-TK mutation status, only if: • the result of an EGFR-TK mutation diagnostic test is unobtainable because of an inadequate tissue sample or poor-quality DNA and • the treating clinician considers that the tumour is very likely to be EGFR-TK mutation-positive and • the person's disease responds to the first 2 cycles of treatment with erlotinib and • the company provides erlotinib with the discount agreed in the patient access scheme revised in the context of NICE technology appraisal guidance 258. Erlotinib is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-negative. Gefitinib is not recommended for treating locally advanced or metastatic non-small-cell lung cancer that has progressed after non-targeted chemotherapy in people with tumours that are EGFR-TK mutation-positive. People whose treatment with erlotinib or gefitinib 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.	September 2006 SMC advice superseded by NICE MTA383, February 2016

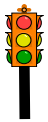
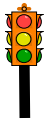
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
erlotinib, 25, 100 and 150mg film-coated tablets (Tarceva®) *Roche* 17.01.11 *SMC Report No. 664/10*	NOT RECOMMENDED: erlotinib (Tarceva®) is not recommended for use within NHS Scotland. Indication under review: as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum-based first-line chemotherapy. Erlotinib maintenance treatment provided a statistically significant increase in progression free survival and overall survival in patients treated with standard first-line platinum-based chemotherapy, both in the whole study population and in a post hoc analysis in patients with stable disease. In the whole study population the changes in these outcomes were considered to be of modest size. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	
erlotinib 25, 100 and 150mg film-coated tablets (Tarceva®) *Roche Products Ltd* 16.01.12 *SMC Report No. 749/11* Patient Access Scheme	Accepted for use: erlotinib (Tarceva®) is accepted for use within NHS Scotland for first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations. In patients with advanced or metastatic NSCLC with EGFR mutations, erlotinib was associated with significantly improved progression-free survival compared with platinum-based doublet chemotherapy regimens. There are no mature overall survival data. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of erlotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only.	March 2012
everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Limited* 10.11.14 *SMC Report No. 595/10* RESUBMISSION	Accepted for use: everolimus (Afinitor®) is accepted for use within NHS Scotland for the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. Everolimus, in conjunction with best supportive care (BSC), increased median progression-free survival (PFS) by three months compared with placebo plus BSC in heavily pre-treated patients with metastatic renal cell carcinoma.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2014
everolimus (Votubia®) 2.5mg and 5mg tablets *Novartis Pharmaceuticals UK Ltd* 09.04.12 *SMC Report No. 787/12* NON SUBMISSION	NOT RECOMMENDED: everolimus (Votubia®) is not recommended for use within NHS Scotland for the treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
everolimus, 5mg, 10mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Limited* 14.05.12 *SMC Report No. 777/12*	Accepted for use: everolimus (Afinitor®) is accepted for use within NHS Scotland for the Treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease. Everolimus was superior to placebo in prolonging progression-free survival in adults with progressive, advanced pNET who were receiving best supportive care.	Included on the Additional List for the indication in question. Specialist Use only.	July 2012
everolimus (Votubia®) 10mg tablets *Novartis Pharmaceuticals Ltd* 10.06.13 *SMC Report No. 884/13* NON SUBMISSION	NOT RECOMMENDED: everolimus (Votubia®) is not recommended for use within NHS Scotland for the treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Limited* 11.04.16 *SMC Report No. 872/13* 2nd RESUBMISSION	Accepted: everolimus (Afinitor®) is accepted for use within NHS Scotland. Indication under review: For the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor. The addition of everolimus to exemestane treatment significantly increased progression free survival compared with exemestane alone in postmenopausal women with disease progression following a non-steroidal aromatase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication 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**
everolimus (Certican®) 0.25mg, 0.5mg and 0.75mg tablets *Novartis Pharmaceuticals UK Ltd* 09.11.15 *SMC Report No. 1117/15* NON SUBMISSION	NOT RECOMMENDED: everolimus (Certican®) is not recommended for use within NHS Scotland. Indication under review: Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a cardiac transplant Prophylaxis of organ rejection in patients receiving a hepatic transplant The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of everolimus for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal transplant and therefore SMC has not issued advice for that indication.	NOT RECOMMENDED	
everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) *Novartis Pharmaceuticals UK Ltd* 13.02.17 *SMC Report No. 1215/17* Patient Access Scheme	Accepted for use: everolimus (Afinitor®) is accepted for use within NHS Scotland for the treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease. Treatment with everolimus improved progression-free survival, when compared with placebo, in patients with progressive, advanced, well-differentiated, non-functioning neuroendocrine tumours of gastrointestinal or lung origin. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of everolimus. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	April 2017
exemestane 25mg tablets (Aromasin®) *Pfizer Limited* 07.11.05 *SMC Report No. 210/05*	Restricted use: Exemestane (Aromasin®) is accepted for restricted use within NHS Scotland for the adjuvant treatment of postmenopausal women with oestrogen receptor positive invasive early breast cancer, following 2 - 3 years of initial adjuvant tamoxifen therapy. Exemestane has shown benefit in terms of disease-free survival when given as an alternative to tamoxifen after initial adjuvant treatment with tamoxifen for 2 - 3 years. It offers an alternative to tamoxifen after initial adjuvant treatment with tamoxifen for 2 - 3 years and has a different adverse effects profile. Treatment with exemestane is restricted to initiation by a breast cancer specialist.	Added to the LJF as a prescribing note.	August 2010

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
febuxostat 120mg film-coated tablet (Adenuric®) *A. Menarini Farmaceutica Internazionale SRL* 13.06.16 *SMC Report No. 1153/16*	Restricted use: febuxostat film-coated tablet (Adenuric®) is accepted for restricted use within NHS Scotland for the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS). SMC restriction: prevention of hyperuricaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated, such as: • Those intolerant of allopurinol • Those in whom allopurinol is contraindicated, e.g. patients with renal impairment In a phase III, randomised, double-blind study in adults with haematologic malignancies at intermediate to high risk of TLS, febuxostat was significantly superior to a xanthine oxidase inhibitor at reducing serum uric acid levels.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	July 2016
fludarabine, 10mg tablet and 50mg for injection or infusion (Fludara®) *Schering Health Care Ltd* 13.11.06 *SMC Report No. 176/05*	Restricted use: fludarabine phosphate (Fludara®) is accepted for restricted use within NHS Scotland for the treatment of B-cell chronic lymphocytic leukaemia (CLL) in patients with sufficient bone marrow reserves. First line treatment should only be initiated in patients with advanced disease, Rai stages III/IV (Binet stage C), or Rai stages I/II (Binet stage A/B) where the patient has disease related symptoms or evidence of progressive disease. Fludarabine phosphate has been associated with higher response rates than chlorambucil in clinical trials. No overall survival advantage over other therapies has been demonstrated. Fludarabine is restricted to use by specialists in haemato-oncology.	Added to the Additional List, for Specialist Use only.	July 2009
FOLFIRINOX combination chemotherapy (Folic acid, 5-Fluorouracil, Irinotecan, Oxaliplatin) *Various*	For use in palliative chemotherapy for inoperable pancreatic adenocarcinoma in good performance status patients.	Added to the Additional List, for Specialist Use only.	December 2011
fosaprepitant, 115mg powder for solution for infusion (Ivemend®) *Merck Sharp & Dohme Limited* 13.10.08 *SMC Report No. 506/08*	Restricted use: fosaprepitant (Ivemend®) is accepted for restricted use within NHS Scotland for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. Fosaprepitant is marginally more expensive than aprepitant. It is restricted to use in patients for whom aprepitant is indicated but the oral formulation is not appropriate. Prescribing should be initiated by hospital based specialists only. Fosaprepitant is also licensed for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. As the manufacturer's submission related only to its use with highly emetogenic cancer chemotherapy, SMC cannot recommend its use in this setting.	Added to the Additional List, for Specialist Use only.	July 2009 PRODUCT WITHDRAWN FROM THE UK MARKET – 15 FEBRUARY 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
fosaprepitant dimeglumine 150 mg powder for solution for infusion (IVEmend®) *MSD Ltd* 07.03.11 *SMC Report No. 678/11* PRODUCT UPDATE (abbreviated submission)	Accepted for use: fosaprepitant dimeglumine (IVEmend 150mg®) is accepted for use within NHS Scotland. Indication under review: Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults. IVEmend 150 mg is given as part of a combination therapy. Fosaprepitant 150mg is not recommended for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults, as SMC has previously not recommended both fosaprepitant iv and aprepitant capsules for this indication.	Added to the Additional List, for Specialist Use only.	March 2011
fulvestrant 250mg solution for injection (Faslodex®) *AstraZeneca UK Limited* 08.02.16 *SMC Report No. 114/04* RESUBMISSION Patient Access Scheme	Accepted for use: fulvestrant (Faslodex®) is accepted for use within NHS Scotland. Indication under review: for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen. In a phase III randomised double blind study, fulvestrant 500mg increased progression free survival and overall survival compared to fulvestrant 250mg. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fulvestrant. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting	Included on the Additional List, Specialist Use only, for the indication in question.	October 2016
gefitinib 250mg film-coated tablets (Iressa®) *AstraZeneca UK Ltd* 07.12.15 *SMC Report No: 615/10* 2nd RESUBMISSION Patient Access Scheme	Restricted: gefitinib (Iressa®) is accepted for restricted use within NHS Scotland. Indication under review: the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK). SMC restriction: in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy. In patients with EGFR mutation-positive, advanced NSCLC, randomised controlled studies demonstrated an improvement in the progression-free survival and tumour response rates for those treated with gefitinib compared with platinum-doublet chemotherapy. There was no overall survival benefit demonstrated. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of gefitinib. 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

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**
gemcitabine (Gemzar®) *Eli Lilly & Co Ltd*	Biliary tract cancer 	It was agreed that gemcitabine (Gemzar®) for biliary tract cancer should be added to the Additional List. Gemcitabine (Gemzar®) for biliary tract cancer has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	September 2005
gemcitabine 200mg and 1g powder for solution for infusion (Gemzar®) *Eli Lilly and Company Ltd* 11.12.06 *SMC Report No. 154/05* RESUBMISSION	Restricted use: gemcitabine (Gemzar®), in combination with paclitaxel, is accepted for restricted use within NHS Scotland for the treatment of patients with metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated. Gemcitabine in combination with paclitaxel modestly improves outcomes, compared to paclitaxel monotherapy, in those previously treated with an anthracycline. For this indication gemcitabine is restricted to use by oncologists specialising in the treatment of breast cancer.	Added to the Additional List, for Specialist Use only.	December 2007
gemcitabine (Gemzar®)	In combination with dexamethasone and cisplatin for relapsed / refractory lymphoma. 	Added to the Additional List, for Specialist Use only. Gemcitabine (Gemzar®) for relapsed / refractory lymphoma 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
gemcitabine powder for infusion and capecitabine tablets Local formulary process	For the adjuvant treatment following potentially curative resection of pancreatic cancer. 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	July 2017
granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) *ProStrakan Ltd* 07.10.13 *SMC Report No. 895/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: granisetron 3.1mg / 24 hours transdermal patch (Sancuso®) is accepted for use within NHS Scotland in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult. Granisetron 3.1mg / 24 hours transdermal patch is slightly more expensive than the oral formulation. It provides an alternative option in patients who have difficulty swallowing oral medication.	Included on the Additional List, Specialist Use only, for the indication in question.	October 2013

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
histamine dihydrochloride, 500 microgram/0.5ml, vial (Ceplene®) *Meda Pharmaceuticals Ltd* 17.01.11 *SMC Report No. 666/10*	NOT RECOMMENDED: histamine dihydrochloride (Ceplene®) is not recommended for use within NHS Scotland. Indication under review: maintenance therapy for adult patients with acute myeloid leukaemia in first remission concomitantly treated with interleukin-2. The efficacy of histamine dihydrochloride has not been fully demonstrated in patients older than age 60 years. In a randomised open-label study, histamine plus interleukin-2 was superior to no treatment for the endpoint of leukaemia free survival (LFS) in a sub-group of patients in first complete remission. In post hoc analysis of patients in first complete remission and aged less than 60 years, LFS rates at 36 months were 50% versus 30%. Overall the manufacturer did not present a sufficiently robust clinical or economic case to gain acceptance by SMC.	NOT RECOMMENDED	
histidine - tryptophan - ketoglutarate (HTK) (Custodial®) *Kohler Medical Ltd*	(1) Non heart-beating kidney - liver donors (NHBD) (2) Live donor liver transplantation (LDLT)	Approved for use in all non heart-beating donation (NHBD) and live donor liver transplantation (LDLT) retrievals, for Specialist Use only. Added to the Additional List.	May 2006
histrelin acetate, 50mg subcutaneous implant (Vantas®) *Orion Pharma (UK) Ltd* 10.08.09 *SMC Report No. 557/09*	Restricted use: histrelin (Vantas®) subcutaneous implant is accepted for restricted use within NHS Scotland for palliative treatment of advanced prostate cancer. Histrelin is restricted to use in patients with an anticipated life expectancy of at least one year in whom annual administration will offer advantages. In a single-arm study, histrelin provided effective suppression of testosterone levels in patients with advanced prostate cancer. It requires less frequent administration than other leutenising hormone releasing hormone (LHRH) agonists. Other LHRH agonists are available at a lower acquisition cost.	'Not preferred' in Lothian as suitable alternatives exist.	January 2010
ibandronic acid (Bondronat®) *Roche* 11.10.04 *SMC Report No. 123/04*	Accepted for use: ibandronic acid is accepted for use within NHS Scotland for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. It reduces the rate of skeletal events consisting of a composite of vertebral fractures, pathological non-vertebral fractures and the need for radiotherapy or surgery to deal with bone complications. It can be given both by the oral or intravenous route.	Added to the Formulary as first choice bisphosphonate, on the advice of an oncologist/ haematologist, for the prevention of skeletal related events in patients with breast cancer.	February 2005
ibritumomab tiuxetan (Zevalin®) *Schering Health Care Ltd* 09.07.07 *SMC Report No. 171/05* RESUBMISSION	NOT RECOMMENDED: ibritumomab tiuxetan (Zevalin®) is not recommended for use within NHS Scotland for the preparation of a radiopharmaceutical incorporating Yttrium 90 [^{90}Y] for the treatment of adult patients with rituximab relapsed or refractory CD20+ follicular B-cell non-Hodgkin's lymphoma (NHL). The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ibritumomab tiuxetan 1.6mg/ml (Zevalin®) *Bayer plc* 11.08.08 *SMC Report No. 449/08* NON SUBMISSION	NOT RECOMMENDED: ibritumomab tiuxetan (Zevalin) is not recommended for use within NHS Scotland as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. 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	
ibrutinib 140mg hard capsule (Imbruvica®) *Janssen-Cilag Ltd.* 08.08.16 *SMC Report No. 1150/16* Patient Access Scheme	Accepted for use: ibrutinib (Imbruvica®) is accepted for use within NHS Scotland for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). In a randomised, open-label, phase III study ibrutinib significantly prolonged progression-free survival, the primary endpoint, compared to a chemotherapy treatment, in patients with relapsed or refractory MCL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only, for the indication in question.	November 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ibrutinib 140mg hard capsules (Imbruvica®) *Janssen-Cilag Ltd.* 08.08.16 *SMC Report No. 1151/16* Patient Access Scheme	Restricted use: ibrutinib (Imbruvica®) is accepted for restricted use within NHS Scotland for treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. SMC restriction: patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy. In an open-label, phase III study, ibrutinib significantly increased progression-free survival compared with an anti-CD20 antibody in patients with relapsed or refractory CLL. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ibrutinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only, for the indication in question: Treatment of adult patients with CLL and with 17p deletion or TP53 mutation, who are unsuitable for chemo-immunotherapy, in the first-line or relapsed setting.	November 2016
10.04.17 *SMC Report No. 1151/16* RESUBMISSION Patient Access Scheme	Treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. SMC restriction: patients with relapsed/refractory CLL and for whom fludarabine-based regimens are inappropriate.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 2017
ibrutinib (Imbruvica®) 140mg hard capsules *Janssen-Cilag Ltd* 12.06.17 *SMC Report No. 1258/17* NON SUBMISSION	In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy.	Not routinely available as not recommended for use in NHSScotland.	May 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
idelalisib 100mg and 150mg tablets (Zydelig®) *Gilead Sciences Ltd.* 09.03.15 *SMC Report No. 1026/15* *Patient Access Scheme*	Restricted use: idelalisib (Zydelig®) is accepted for restricted for use within NHS Scotland in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • who have received at least one prior therapy, or • as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. SMC restriction: patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy. Idelalisib in combination with an anti-CD20 antibody significantly improves progression free survival compared with an anti-CD20 antibody alone in patients with relapsed CLL. The treatment effect across subgroups with 17p deletion and/or TP53 mutation was consistent with that of the total study population. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idelalisib. It is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, specialist use only.	September 2015
idelalisib, 100mg and 150mg film-coated tablets (Zydelig®) *Gilead Sciences Ltd.* 11.05.15 *SMC Report No. 1039/15* Patient Access Scheme	Restricted use: idelalisib (Zydelig®) is accepted for use within NHS Scotland. Indication under review: Monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment. Idelalisib demonstrated clinical activity, measured by overall response rate, in a phase II non-comparative study. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idelalisib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2015
idelalisib (Zydelig®) 100mg, 150mg film-coated tablets *Gilead Sciences Ltd* 12.12.16 *SMC Report No. 1212/16* NON SUBMISSION	NOT RECOMMENDED: idelalisib (Zydelig®) is not recommended for use within NHS Scotland in combination with ofatumumab for the treatment of adult patients with chronic lymphocytic leukaemia: • who have received at least one prior therapy, or • first line treatment in the presence of 17p deletion or TP53 mutation in patients who are not eligible for any other therapies. 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**
imatinib (Glivec®) *Novartis* 08.03.02 *SMC Report No. 01/02* and 10.01.03 *SMC Report No. 26/02*	Restricted use: imatinib (Glivec®) is recommended for restricted use within the NHS in Scotland. Imatinib is the first treatment to offer major cytogenetic responses in chronic myeloid leukaemia. This approach appears to provide a significant advance in the treatment of a hitherto fatal haematological malignancy. This licence extension has been granted on the basis of interim analyses which show superiority of imatinib over interferon combination therapy in terms of cytogenetic and haematological response. Imatinib should be used only by or under the direction of haematologists/oncologists experienced in this field. There should be a formal process of audit and monitoring with a central registry of all patients receiving it and/or entry into a clinical trial.	Approved for use - added to the Additional List.	January 2003
imatinib (Glivec®) *Novartis* 09.08.03 *SMC Report No. 08/02*	Restricted use: imatinib (Glivec®) is recommended for restricted use within the NHS in Scotland, under the supervision of an oncologist for patients with Kit-positive gastrointestinal stromal tumours (GIST).	Approved for use - added to the Additional List.	
imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* 10.12.07 *SMC Report No. 426/07* NON SUBMISSION	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) as monotherapy. 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	
imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* 10.12.07 *SMC Report No. 427/07* NON SUBMISSION	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (PH + ALL) in combination with chemotherapy. 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	
imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* 10.12.07 *SMC Report No. 428/07* NON SUBMISSION	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. 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	
imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* 10.12.07 *SMC Report No. 429/07* NON SUBMISSION	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement. 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	

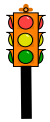
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd* 10.12.07 *SMC Report No. 430/07* NON SUBMISSION	NOT RECOMMENDED: Imatinib (Glivec®) is not recommended for use within NHSScotland for the treatment of adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
imatinib 100mg and 400mg film-coated tablets (Glivec®) Novartis Pharmaceuticals UK Ltd 07.12.09 *SMC Report No. 584/09* RESUBMISSION	Restricted use: imatinib (Glivec®) is accepted for restricted use within NHS Scotland. Indication under review: adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. SMC restriction: Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria). Imatinib, given for a period of one year, significantly improved the estimated one year recurrence-free survival compared with placebo and was associated with an increase of 16.4 months in median time to recurrence in patients at high risk of relapse following resection. The economic case was demonstrated for a one-year adjuvant treatment duration only.	Added to the Additional List, Specialist Use only	April 2011
imatinib 100mg and 400mg film-coated tablets (Glivec®) Novartis Pharmaceuticals UK Ltd 09.04.12 *SMC Report No. 584/09* 2nd RESUBMISSION	Restricted use: imatinib (Glivec®) is accepted for restricted use within NHS Scotland. Indication under review: adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. SMC restriction: Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria). Adjuvant imatinib therapy given for a period of three years compared to one year, significantly improved the recurrence free survival in adult patients at significant risk of relapse following resection of GIST. The clinical and cost-effectiveness of three years adjuvant imatinib treatment was demonstrated.	Included on the Additional List for the indication in question. Specialist Use only. See SMC advice above. Same SMC Report Number – this advice relates to an extension in treatment length to 3 years.	July 2012
imatinib (Glivec®) 100 mg / 400 mg film coated tablets *Novartis Pharmaceuticals UK Ltd* 07.10.13 *SMC Report No. 923/13* NON SUBMISSION	NOT RECOMMENDED: imatinib (Glivec®) is not recommended for use within NHS Scotland for the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. 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**
imiquimod 5% cream (Aldara®) *3M Health Care* 09.05.05 SMC Report No. 167/05	Restricted use: imiquimod 5% (Aldara®) is accepted for restricted use within NHS Scotland for the topical treatment of small superficial Basal Cell Carcinoma in adult patients in whom standard treatment with surgery or cryotherapy is contraindicated. Its use should be supervised by specialists in dermatology. At 12 weeks post treatment the composite clearance rates in the randomised controlled trials were between 73-77% and initial clearance rates in the open label studies were between 90-94%. There is only limited follow-up data beyond 12 months.	Added to the LJF as a Prescribing Note.	September 2005
ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) *Bristol-Myers Squibb* 08.04.13 *SMC Report No. 779/12* RESUBMISSION Patient Access Scheme	Accepted for use: ipilimumab (Yervoy®) is accepted for use within NHS Scotland for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. Ipilimumab demonstrated a survival benefit over an investigational glycoprotein100 peptide vaccine in previously treated patients with advanced melanoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ipilumumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	Included on the Additional List, Specialist Use only, for the indication in question.	June 2013
ipilimumab 5mg/mL concentrate for solution for infusion (Yervoy®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 10.11.14 *SMC Report No. 997/14* Patient Access Scheme	Accepted for use: ipilimumab (Yervoy®) is accepted for use within NHS Scotland for the treatment of advanced (unresectable or metastatic) melanoma in adults (first-line use). In a phase III, randomised study median overall survival was extended by 2.1 months in patients treated with ipilimumab plus dacarbazine (an unlicensed dose regimen) compared with dacarbazine alone. Efficacy data for the licensed dose of ipilimumab are limited to two retrospective single-arm observational studies where median overall survival was 11.5 to 14.3 months. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Ipilimumab. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2014
lanreotide (Somatuline® LA) *Ipsen Ltd* 11.12.06 *SMC Report No. 231/06* NON SUBMISSION	NOT RECOMMENDED: lanreotide (Somatuline® LA) is not recommended for use within NHSScotland for the treatment of thyrotrophic adenomas when the circulating level of thyroid stimulating hormone remains inappropriately high after surgery and/or radiotherapy. 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	
lanreotide autogel	Management of neuroendocrine tumours.	Included on the LJF, as first choice, for the indication in question	March 2016

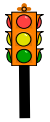
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
lapatinib, 250mg film-coated tablets (Tyverb®) *GlaxoSmithKline* 13.07.10 *SMC Report No. 526/09* RESUBMISSION	NOT RECOMMENDED: lapatinib (Tyverb®) is not recommended for use within NHS Scotland. Indication under review: in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have progressive disease following prior therapy including anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. In a randomised open-label study the median time to progression for lapatinib plus capecitabine was significantly longer than for capecitabine monotherapy. There was no statistically significant difference in overall survival. Compared with capecitabine monotherapy, the manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. There was also uncertainty about the comparative effectiveness and cost-effectiveness compared to unlicensed use of trastuzumab and capecitabine in patients with metastatic disease confined to the central nervous system, itself a treatment of unproven cost-effectiveness.	NOT RECOMMENDED	
lapatinib (Tyverb®) 250 mg film-coated tablets *GlaxoSmithKline* 13.02.12 *SMC Report No. 768/12* NON SUBMISSION	NOT RECOMMENDED: lapatinib (Tyverb®) 250 mg film-coated tablets is not recommended for use within NHS Scotland for the Treatment of patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of lapatinib in this indication. However due to the significant time interval between product availability and the expected date of NICE guidance, not recommended advice has been issued. 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	
lapatinib (Tyverb®) 250 mg film-coated tablets *GlaxoSmithKline* 11.11.13 *SMC Report No. 925/13* NON SUBMISSION	NOT RECOMMENDED: lapatinib (Tyverb®) is not recommended for use within NHS Scotland for the treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy. 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**
lenalidomide, 7.5mg, 10mg, 15mg and 25mg hard capsules (Revlimid®) *Celgene Limited* 07.04.14 *SMC Report No. 441/08* 2nd RESUBMISSION	Restricted use: lenalidomide (Revlimid®) is accepted for restricted use within NHS Scotland in combination with dexamethasone, for the treatment of multiple myeloma in adult patients who have received at least one prior therapy. (This resubmission relates to patients who have received only one prior therapy). SMC restriction: to use at first relapse in patients who have received prior therapy with bortezomib in whom thalidomide has not been tolerated or is contraindicated. Lenalidomide plus dexamethasone significantly increased the time to progression compared with dexamethasone alone in multiple myeloma patients who had been treated with at least one prior therapy. SMC has previously accepted lenalidomide for use in patients who have received at least two prior lines of therapy i.e. at second relapse. This advice now extends its use to patients at first relapse who received bortezomib as their one prior therapy.	For use in patients who have received at least two prior lines of therapy. Added to the Additional List, for Specialist Use only. For patients who have received only one prior therapy - **Not included** on the LJF, pending protocol.	September 2010 July 2014
lenalidomide, 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg capsules (Revlimid®) *Celgene Europe Limited* 07.12.15 *SMC Report No. 1096/15*	Restricted: lenalidomide (Revlimid®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. SMC restriction: for use in patients unsuitable for thalidomide-containing regimens Continuous lenalidomide plus low-dose dexamethasone, compared with melphalan, prednisolone plus thalidomide, significantly improved progression-free survival in treatment-naive patients with newly diagnosed multiple myeloma who were not eligible for transplant. Overall survival data are immature, but interim analyses suggest a survival benefit for lenalidomide plus low-dose dexamethasone compared with melphalan, prednisolone plus thalidomide. This submission focuses on lenalidomide in combination with dexamethasone. Lenalidomide is also licensed for use in combination with melphalan and prednisolone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. The submitting company did not provide evidence for SMC assessment therefore SMC cannot recommend this combination for use in this treatment setting. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the additional list, Specialist use only, for the indication in question.	April 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**
lenalidomide (Revlimid®) 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules *Celgene Ltd* 07.11.16 *SMC Report No. 1211/16* NON SUBMISSION	NOT RECOMMENDED: lenalidomide (Revlimid®) is not recommended for use within NHS Scotland for the treatment of adult patients with relapsed or refractory mantle cell lymphoma. 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	
lenvatinib 4mg and 10mg hard capsules (Lenvima®) *Eisai Ltd.* 10.10.16 *SMC Report No. 1179/16* Patient Access Scheme	Accepted for use: lenvatinib (Lenvima®) is accepted for use within NHS Scotland for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). Lenvatinib, compared with placebo, significantly improved progression free survival in adults with RAI-refractory DTC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of lenvatinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only, for the indication in question.	November 2016
letrozole 2.5mg tablets (Femara®) *Novartis Pharmaceuticals (UK) Ltd* 07.03.05 *SMC Report No. 152/05*	Restricted use: letrozole (Femara®) is accepted for restricted use within NHS Scotland for the treatment of invasive early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy. Treatment should continue for 3 years or until tumour relapse, whichever occurs first. Following 5 years of adjuvant tamoxifen therapy the risk of recurrence (in ipsilateral breast, new tumour in contralateral breast or distance metastases) occurs at an aggregate rate of 2- 3% per year. The use of letrozole as extended adjuvant treatment resulted in a 43% lower risk of recurrence compared with placebo. However, a significant difference for overall survival, defined as time to death from any cause, was seen in lymph-node positive patients only. Clinicians and patients should consider the residual risk of recurrence, individual preferences and the risks and benefits of treatment. Letrozole is restricted to initiation to breast cancer specialists.	Added to the Formulary as a Prescribing Note. Shared care protocol to be developed.	August 2005

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**
letrozole 2.5mg tablets (Femara®) *Novartis Pharmaceuticals UK Ltd* 08.05.06 *SMC Report No. 251/06*	Restricted use: letrozole (Femara®) is accepted for restricted use within NHS Scotland for the adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer. Letrozole has shown benefit over standard anti-oestrogen therapy in terms of disease-free survival, although a pre-planned sub-group analysis showed a statistically significant beneficial effect in node-positive but not node-negative patients. It offers an alternative to existing treatment and has a different range of adverse effects. Another aromatase inhibitor is available for the same indication at a lower cost. Treatment with letrozole should be initiated by a breast cancer specialist.	Added to the LJF as first choice for patients at risk of early recurrence or with a contraindication to tamoxifen. Letrozole also first choice for extended adjunvant treatment after 5 years treatment with tamoxifen.	August 2010
letrozole 2.5mg tablets	For epithelial ovarian cancer. 	Added to the Additional List, for Specialist initiation. Letrozole has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	December 2016
levofloxacin (Tavanic®) *Hoechst Marion Roussel*	Antibiotic prophylaxis for neutropenic sepsis in lung cancer patients undergoing chemotherapy only.	Not preferred as suitable alternatives exist.	December 2006
lipegfilgrastim, 6mg, solution for injection (Lonquex®) *Teva Pharma BV* 07.04.14 *SMC Report No. 908/13*	Restricted use: lipegfilgrastim (Lonquex®) is accepted for restricted use within NHS Scotland for reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). SMC restriction: where a long-acting granulocyte-colony-stimulating factor is appropriate. In a randomised, double-blind study, in adults with breast cancer given myelosuppressive chemotherapy associated with a high risk of febrile neutropenia, lipegfilgrastim was compared with another long-acting granulocyte colony-stimulating factor when used as primary prophylaxis against febrile neutropenia. The study found lipegfilgrastim was non-inferior to the comparator preparation in terms of the mean duration of severe neutropenia in the first chemotherapy cycle.	Included on the additional list, Specialist Use only.	March 2016
liposomal cytarabine 50mg suspension for injection (DepoCyte®) *Napp Pharmaceuticals* 13.08.07 *SMC Report No. 164/05* RESUBMISSION	NOT RECOMMENDED: liposomal cytarabine suspension (DepoCyte®) is not recommended for use within NHS Scotland for the intrathecal treatment of lymphomatous meningitis. There is limited clinical evidence to support a claim of superior efficacy for liposomal cytarabine over existing therapy. Effects on symptom improvement and quality of life were not well defined. The manufacturer did not present a sufficiently robust economic analysis and its justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
liposomal irinotecan hydrochloride trihydrate (as irinotecan sucrosofate salt), 5mg/mL concentrate for solution for infusion (Onivyde®) *Shire* 13.03.17 *SMC Report No. 1217/17*	Treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil (5-FU) and leucovorin (folinic acid), in adult patients who have progressed following gemcitabine based therapy.	NOT RECOMMENDED	April 2017
mercaptopurine 20mg/mL oral suspension (Xaluprine®) *Nova Laboratories Limited* 13.08.12 *SMC Report No. 798/12* PRODUCT UPDATE (abbreviated submission)	Accepted for use: mercaptopurine 20mg/mL oral suspension (Xaluprine®) is accepted for use within NHS Scotland for the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children. Mercaptopurine dosing is governed by cautiously monitoring haematotoxicity. The oral suspension and tablet formulations are not bioequivalent in terms of peak plasma concentrations and therefore careful haematological monitoring of the patient is advised on switching formulations. Mercaptopurine oral suspension is more expensive than the tablet formulation.	Included on the Additional List for the indication in question, where an oral suspension is required.	August 2012
methotrexate 2mg/mL oral solution	As treatment of acute lymphoblastic leukaemia and inflammatory arthritis.	Included on the LJF For acute lymphoblastic leukaemia: on the additional list. For inflammatory arthritis: as first choice, Specialist initiation.	March 2016
methyl aminolevulinate cream (Metvix®) *Galderma* 10.11.03 *SMC Report No. 51/03* RESUBMISSION	Restricted use: methyl aminolevulinate cream (Metvix®) appears to be effective for the treatment of basal cell carcinoma in those patients in whom standard treatment with surgery or cryotherapy is contraindicated. Its use should be restricted to specialist dermatologists and to superficial lesions where penetration is most effective.	Added to the Additional List.	October 2005
mifamurtide, 4mg powder for suspension for infusion (Mepact®) *Takeda UK and Ireland Ltd* 08.08.11 *SMC Report No. 621/10* RESUBMISSION Patient Access Scheme	Accepted for use: mifamurtide (Mepact) is accepted for use within NHS Scotland. Indication under review: in combination with post-operative multi-agent chemotherapy for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection, in children, adolescents and young adults. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis. Mifamurtide has been shown to increase overall survival compared with multi-agent chemotherapy alone in patients aged up to 30 years with newly-diagnosed resectable osteosarcoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mifamurtide. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only.	September 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
mitotane 500mg tablets (Lysodren®) *Laboratoire HRA Pharma* 11.12.06 *SMC Report No. 328/06*	NOT RECOMMENDED: mitotane (Lysodren®) is not recommended for use within NHS Scotland for the symptomatic treatment of advanced (unresectable, metastatic or relapsed) adrenal cortical carcinoma. The effect of mitotane on non-functional adrenal cortical carcinoma is not established. Mitotane relieves the symptoms of advanced adrenal cortical carcinoma, but there is insufficient evidence to support an increase in survival. The economic case has not been demonstrated. Mitotane should be used only within the context of clinical trials.	NOT RECOMMENDED	
mycophenolate mofetil (CellCept ®) *Roche*	Management of steroid-dependent nephrotic syndrome in paediatric patients. 	Added to the Additional List and prescribed in accordance with Shared Care Protocol. Mycophenolate mofetil has been categorised **AMBER** for **paediatrics** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2012
mycophenolic acid (as mycophenolate sodium), 180mg and 360mg film-coated gastro-resistant tablets (Myfortic®) *Novartis Pharmaceuticals UK Limited* 07.02.05 *SMC Report No. 144/04*	Accepted for use: mycophenolate sodium (Myfortic®) is accepted for use within NHS Scotland for the prophylaxis of acute transplant rejection in adult patients receiving allogenic renal transplants in combination with ciclosporin and corticosteroids. It is restricted to use by transplant specialists as part of an immunosuppressive regimen.	Added to the Additional List. Suitable for shared care protocol.	March 2012
necitumumab (Portrazza®) 800mg concentrate for solution for infusion *Eli Lilly and Company Limited* 08.08.16 *SMC Report No. 1184/16* NON SUBMISSION	NOT RECOMMENDED: necitumumab (Portrazza®) is not recommended for use within NHS Scotland in combination with gemcitabine and cisplatin chemotherapy for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer who have not received prior chemotherapy for this condition. 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	
nelarabine, 5mg/ml solution for infusion (Atriance®) *GlaxoSmithKline UK* 07.04.08 *SMC Report No. 454/08*	Restricted use: nelarabine (Atriance®) is accepted for restricted use within NHS Scotland for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to, or has relapsed following, treatment with at least two chemotherapy regimens. It is restricted to patients in whom nelarabine is being used as a treatment to bridge to allogeneic stem cell transplant and restricted to use by specialists in haemato-oncology. It is not cost-effective when used for palliation.	Added to the Additional List, Specialist use only.	November 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**
netupitant/palonosetron 300mg/0.5mg, hard capsule (Akynzeo®) *Chugai Pharma UK Limited* 11.01.16 *SMC Report No. 1109/15* Patient Access Scheme	Restricted use: netupitant/palonosetron (Akynzeo®) is accepted for restricted use within NHS Scotland. Indication under review: in adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy. SMC restriction: prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. In patients receiving a first course of highly emetogenic cisplatin-based chemotherapy, treatment with netupitant/palonosetron plus dexamethasone resulted in a significantly higher proportion of patients achieving no emesis and no breakthrough medication compared with palonosetron plus dexamethasone. This advice takes account of the benefits of Patient Access Scheme (PAS) that improves the cost-effectiveness of netupitant/palonosetron. 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.	Included on the Additional List, for Specialist Use only, for the indication in question.	July 2016
nilotinib, 200mg capsules (Tasigna®) *Novartis Pharmaceuticals UK Ltd* 09.06.08 *SMC Report No. 440/08* *Superseded by MTA 241 Januray 2012*	Restricted use: nilotinib (Tasigna®) is accepted for restricted use within NHS Scotland for treatment of chronic phase Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. It should be restricted to use in patients who are in the chronic phase of the disease. The manufacturer has not made a submission for use in the accelerated phase. As a result we cannot recommend its use within NHSScotland. MTA 241 Nilotinib is recommended for the treatment of chronic or accelerated phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in adults: whose CML is resistant to treatment with standard-dose imatinib or who have imatinib intolerance and if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme.	Added to the Additional List, for Specialist Use only. MTA 241 supersedes SMC advice , FC decision is still valid	March 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**
nilotinib 150mg hard capsules (Tasigna®) *Novartis Pharmaceuticals UK Ltd* 08.08.11 *SMC Report No. 709/11* Patient Access Scheme	Accepted for use: nilotinib 150mg hard capsules (Tasigna®) is accepted for use within NHS Scotland. Indication under review: for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase. First-line treatment with nilotinib in newly diagnosed patients has resulted in significantly higher molecular and cytogenetic response rates compared to the standard tyrosine kinase inhibitor. Further longer term follow-up data are needed to confirm the duration of this response and assess the impact on disease progression and overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nilotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.	Added to the Additional List, for Specialist Use only.	November 2011
nintedanib 100mg and 150mg soft capsules (Vargatef®) *Boehringer Ingelheim International GmbH* 13.04.15 *SMC Report No. 1027/15* Patient Access Scheme	Accepted for use: nintedanib (Vargatef®) is accepted for use within NHS Scotland in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy. Addition of nintedanib to second-line treatment of stage IIIb/IV NSCLC with docetaxel significantly increased overall survival in the subgroup patients with adenocarcinoma tumour histology. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of nintedanib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, specialist use only, for the indication in question.	July 2015

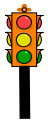
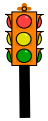
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 08.08.16 *SMC Report No. 1120/16* RESUBMISSION Patient Access Scheme	Restricted use; nivolumab (Opdivo®) is accepted for restricted use within NHS Scotland as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. SMC restriction: patients previously untreated with ipilimumab. In a phase III randomised double-blind study, treatment with nivolumab extended overall survival compared with a palliative chemotherapy in patients with previously untreated advanced melanoma without a BRAF mutation. In an ongoing open label phase III study, treatment with nivolumab, at the time of primary analysis, extended overall response rate, compared with investigator's choice of chemotherapy in patients with advanced melanoma previously treated with an anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) treatment or an anti-CTLA-4 treatment and a BRAF inhibitor. The base-case economic analysis submitted by the company assumed that patients were treated for a maximum of two years. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Not included on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question. The current LJF choice is pembrolizumab.	October 2016
nivolumab 40mg/4mL and 100mg/10mL vials of concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceuticals Ltd.* 11.07.16 *SMC Report No. 1144/16* Patient Access Scheme	Accepted for use: nivolumab (Opdivo®) is accepted for use within NHS Scotland for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. Nivolumab, compared with a standard second-line chemotherapy, significantly increased overall survival in patients with locally advanced or metastatic squamous NSCLC who had received previous therapy including platinum-based doublet chemotherapy. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. 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**
nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceutical Limited* 10.10.16 *SMC Report No. 1180/16* Patient Access Scheme	Restricted use: nivolumab (Opdivo®) is accepted for restricted use within NHS Scotland for the treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. SMC restriction: treatment with nivolumab is subject to a two-year clinical stopping rule. Nivolumab, compared with a standard, second-line chemotherapy, significantly increased overall survival in patients with locally advanced or metastatic non-squamous NSCLC who had received previous therapy including platinum-based doublet chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	January 2017
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceutical Limited* 07.11.16 *SMC Report No. 1187/16* Patient Access Scheme	Restricted use: nivolumab (Opdivo®) is accepted for restricted use within NHS Scotland in combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults. SMC restriction: for the first-line treatment of advanced melanoma In a randomised, double-blind, phase III study of adults with previously untreated advanced melanoma nivolumab in combination with ipilimumab was associated with a clinically important and statistically significant improvement in progression-free survival when compared with a single-agent immunotherapy. Overall survival data are immature. The base-case economic analysis submitted by the company assumed that responding patients were treated for a maximum of 18 months. SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of nivolumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	January 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceutical Limited* 12.06.17 *SMC Report No. 1188/16* RESUBMISSION	As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	August 2017
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceutical Limited* 10.07.17 *SMC Report No. 1240/17* Patient Access Scheme	Treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.	Formulary classification not yet decided – waiting for information from clinicans.	
nivolumab, 10mg/mL concentrate for solution for infusion (Opdivo®) *Bristol-Myers Squibb Pharmaceutical Limited* 11.09.17 *SMC Report No 1261/17* Patient Access Scheme	As monotherapy, for the treatment of squamous cell cancer of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy. SMC restriction: treatment with nivolumab is subject to a two year clinical stopping rule. A phase III randomised study demonstrated significantly improved overall survival in patients receiving nivolumab compared with investigator choice of treatment (taxane, folic acid antagonist or epidermal growth factor receptor monoclonal antibody) in adults with SCCHN who had progressed within six months after platinum-based therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nivolumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Formulary classification not yet decided – waiting for information from clinicans	
obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) *Roche Products Limited* 08.12.14 *SMC Report No. 1008/14*	Accepted for use: obinutuzumab (Gazyvaro®) is accepted for use within NHS Scotland in combination with chlorambucil, obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) and with comorbidities making them unsuitable for full-dose fludarabine based therapy. The combination of obinutuzumab plus chlorambucil produced a statistically and clinically significant increase in progression free survival compared with an alkylating agent alone or an alkylating agent/antibody combination, in older patients with previously untreated CLL who had substantial comorbidities.	Included on the Additional List, for Specialist Use only, for the indication in question.	January 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**
obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) *Roche Products Ltd.* 13.03.17 *SMC Report No. 1219/17* Patient Access Scheme	In combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017
ofatumumab, 100mg concentrate for solution for infusion (Arzerra®) *GlaxoSmithKline* 09.08.10 *SMC Report No. 626/10*	NOT RECOMMENDED: ofatumumab (Arzerra®) is not recommended for use within NHS Scotland. Indication under review: the treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and alemtuzumab. Interim analysis of a non-randomised, single-arm small study in a subgroup of patients refractory to fludarabine and alemtuzumab found that ofatumumab produced a response rate of 58%. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and in addition the manufacturer did not present a sufficiently robust economic analysis.	NOT RECOMMENDED	
ofatumumab 100mg and 1,000mg concentrate for solution for infusion (Arzerra®) *Novartis* 11.05.15 *SMC Report No. 1037/15* *Patient Access Scheme*	Restricted use: ofatumumab (Arzerra®) is accepted for restricted use within NHS Scotland. Indication under review: ofatumumab in combination with chlorambucil or bendamustine is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have not received prior therapy and who are not eligible for fludarabine-based therapy. SMC restriction: for use in patients who would not be considered for bendamustine therapy and who would receive chlorambucil-based therapy. The combination of ofatumumab plus chlorambucil produced a statistically and clinically significant increase in progression free survival compared with an alkylating agent alone in older patients with previously untreated CLL who had co-morbidities. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ofatumumab and it is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Not included because clinicians do not support the formulary inclusion. The LJF choise is obinutuzumab.	July 2015
ofatumumab (Arzerra®) 100mg & 1000mg concentrate for solution for infusion *Novartis Pharmaceuticals UK Ltd* 10.04.17 *SMC Report No. 1237/17* NON SUBMISSION	Treatment of adult patients with relapsed CLL in combination with fludarabine and cyclosphosphamide.	NOT RECOMMENDED	April 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
olaparib, 50mg, hard capsules (Lynparza®) *AstraZeneca UK* 07.11.16 *SMC Report No. 1047/15* RESUBMISSION Patient Access Scheme	Accepted for use: olaparib (Lynparza®) is accepted for use within NHS Scotland as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy. Olaparib was assessed in a phase II randomised, placebo-controlled study of patients with high grade serous, recurrent, platinum-sensitive ovarian, fallopian-tube or primary peritoneal cancer in which there had been an objective response to the most recent platinum-based chemotherapy regimen. In a pre-planned analysis of the sub-group of patients with BRCA mutation, olaparib was associated with a significantly improved progression-free survival compared with placebo. An interim analysis of overall survival in the BRCA mutation sub-group (70% maturity) demonstrated a benefit of more than four months for olaparib over placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of olaparib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	January 2017
ondansetron 4mg, 8mg orodispersible films (Setofilm®) *Norgine* 11.11.13 *SMC Report No 912/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: ondansetron orodispersible films (Setofilm®) are accepted for restricted use within NHS Scotland for the use: In adults: • Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy. • Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy. • Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV). In paediatric populations: • Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥4 years. SMC restriction: ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing. Generic preparations of ondansetron are available at a lower cost than the proprietary products.	Included on the Additional List, for the indication in question.	November 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**
osimertinib 40mg and 80mg film-coated tablets (Tagrisso®) *AstraZeneca UK Limited* 13.02.17 *SMC Report No 1214/17* Patient Access Scheme	Restricted use: osimertinib (Tagrisso®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC). SMC Restriction: in patients who have received previous treatment with an EGFR tyrosine kinase inhibitor. Osimertinib was associated with an overall response rate of 66% in the pooled analysis of two phase II single-arm studies of patients with EGFR T790M advanced NSCLC who had received previous treatment with an EGFR tyrosine kinase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of osimertinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	April 2017
oxaliplatin 50mg, 100mg powder for intravenous infusion (Eloxatin®) *Sanofi-aventis* 07.11.05 *SMC Report No. 211/05*	Accepted for use: oxaliplatin (Eloxatin®) is accepted for use within NHS Scotland, in combination with fluorouracil and folinic acid, for the adjuvant treatment of stage III (Dukes' C) colon cancer after complete resection of the primary tumour. Addition of oxaliplatin to a standard regimen of fluorouracil and folinic acid increased disease-free survival in patients who had undergone complete resection of stage III (Dukes' C) colon cancer. An economic evaluation demonstrated that this is a cost effective treatment option for these patients. Treatment with oxaliplatin (Eloxatin®) should be under the supervision of an oncologist.	Added to the Additional List, for Specialist Use only.	November 2005
oxaliplatin (Eloxitan®) *Sanofi Aventis*	Oesophagogastric cancer 	Added to the Additional List. Oxaliplatin (Eloxitan®) (for use in oesophagogastric cancer) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	May 2006
oxaliplatin (Eloxitan®) *Sanofi Aventis*	Treatment of metastatic or locally advanced inoperable oesophagogastric carcinoma (in combination with epirubicin and capecitabine (EOX)) 	Added to the Additional List - Categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2009

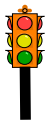
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
oxaliplatin, 5-fluorouracil and folinic acid, a combination chemotherapy regimen	Second-line chemotherapy for patients with pancreatic cancer who have progressed after first–line gemcitabine-based chemotherapy and are of very good performance status. 	Added to the Additional List for Specialist Use only. A combination chemotherapy regimen using oxaliplatin, 5-fluorouracil and folinic acid has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	July 2013
oxycodone (OxyNorm®) *Napp Pharmaceuticals* 11.10.04 *SMC Report No. 125/04*	Restricted use: oxycodone (OxyNorm®) injection is accepted for restricted use within NHS Scotland only for the treatment of moderate to severe pain in patients with cancer. Use of this drug should be restricted to patients who have difficulty in tolerating morphine or diamorphine therapy. Limited data indicate that it provides analgesia similar to parenteral morphine at similar doses. However, there are no comparative data with diamorphine, the opioid recommended by Scottish Intercollegiate Guidelines Network (SIGN) for patients with cancer who require parenteral opioids. Oxycodone is more expensive than diamorphine and the economic case for this product replacing the other products has not been clearly demonstrated. Other indications for this medicine, treatment of moderate to severe post-operative pain and severe pain requiring the use of strong opioid, have yet to be considered by the Scottish Medicines Consortium. Advice on these indications will be made after the relevant submissions have been made by the licence holder.	Added to the Formulary for palliative care. To be initiated by Specialists in patients unable to tolerate morphine or diamorphine therapy.	November 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**
oxycodone hydrochloride 50mg/ml solution for injection or infusion (OxyNorm®) *Napp Pharmaceuticals Limited* 08.11.10 *SMC Report No. 648/10*	Restricted use: oxycodone hydrochloride 50mg/ml injection (OxyNorm®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of moderate to severe pain in patients with cancer SMC restriction: patients who have difficulty in tolerating morphine or diamorphine therapy and who require a high dose of oxycodone delivered via syringe pump which necessitates the daily preparation of an additional syringe pump if oxycodone 10mg/mL is used. No new clinical or pharmacokinetic evidence has been presented for this higher strength formulation. Comparative evidence of analgesia achieved with parenteral administration is extrapolated from the lower strength 10mg/mL oxycodone formulation compared with morphine 10mg/mL. The economic case was made only for patients in a hospice or community setting who require a high dose of oxycodone which necessitates the daily preparation of an additional syringe pump. Care should be taken to minimise any risk of administration error with the introduction of this increased strength formulation. Oxycodone 50mg/mL is also licensed for the treatment of moderate to severe post-operative pain and severe pain requiring the use of strong opioid. The manufacturer's submission related only to use in moderate to severe pain in patients with cancer therefore SMC cannot recommend the use of oxycodone 50mg/mL injection in the treatment of non-cancer pain.	'Not preferred' in Lothian as suitable alternatives exist.	August 2011
paclitaxel (Abraxane®) *Abraxis BioScience Limited* 12.04.10 *SMC Report No. 556/09*	Restricted use: paclitaxel albumin (Abraxane®) is accepted for restricted use within NHS Scotland. Licensed indication under review: the treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated. SMC restriction: Use is restricted to patients who would otherwise receive docetaxel or 3-weekly solvent-based paclitaxel as second-line treatment for metastatic breast cancer. In one study the overall response rate for paclitaxel albumin was significantly superior to solvent-based paclitaxel in a subgroup analysis of patients who had previously received one or more lines of therapy for metastatic disease. The health economic case was only demonstrated for a subset of the licensed indication which is the basis for the SMC restriction. Note that paclitaxel albumin may have substantially different pharmacological properties compared to other formulations of paclitaxel and is licensed for use in a 3-weekly dosage schedule.	Added to the Additional List for Specialist Use only. For use where docetaxel or solvent-based paclitaxel would otherwise be given.	September 2010

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
paclitaxel albumin (Abraxane®) *Celgene Ltd.* 08.06.15 *SMC Report No. 1071/15* NON SUBMISSION	NOT RECOMMENDED: paclitaxel albumin (Abraxane®) is not recommended for use within NHS Scotland. Indication under review: in combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation 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	
paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®) *Celgene Ltd.* 09.02.15 *SMC Report No. 968/14* RESUBMISSION	Accepted for use: paclitaxel albumin (Abraxane®) is accepted for use within NHS Scotland in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. In a randomised, phase III, open-label study paclitaxel albumin plus gemcitabine treatment improved median overall survival by 1.8 months compared with gemcitabine alone. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2015
palifermin (Kepivance®) *Amgen Ltd* 08.05.06 *SMC Report No. 272/06* NON SUBMISSION	NOT RECOMMENDED: palifermin (Kepivance®) is not recommended for use within NHSScotland for the treatment of oral mucositis in bone marrow transplantation. 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	
palonosetron 250micrograms solution for injection (Aloxi®) *Cambridge Laboratories* 07.11.05 *SMC Report No. 208/05*	Accepted for use: Palonosetron (Aloxi®) is accepted for use within NHS Scotland for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. It is as effective as other 5HT3 antagonists in preventing emesis when given as a single intravenous injection following highly emetogenic chemotherapy (HEC) in the acute phase and moderately emetogenic chemotherapy (MEC) in the acute and delayed phases post-chemotherapy.	Added to the Additional List, for Specialist Use only.	July 2008
palonosetron 500microgram soft capsules (Aloxi®) *Sinclair IS Pharma* 11.02.13 *SMC Report No. 838/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: palonosetron soft capsules (Aloxi®) is accepted for use within NHS Scotland for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults. At recommended licensed doses the soft capsule formulation has been shown to be clinically non-inferior to the intravenous formulation and is cost neutral. SMC has previously accepted palonosetron intravenous injection for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.	Included on the Additional List for the indication in question.	January 2013

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
palonosetron, 250 micrograms solution for injection (Aloxi®) *Chugai Pharma UK Limited* 10.08.15 *SMC Report No. 1073/15* PRODUCT UPDATE (abbreviated submission)	Accepted for use: palonosetron (Aloxi®) is accepted for use within NHS Scotland. Indication under review: prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, in paediatric patients 1 month of age and older. A phase III double blind study demonstrated non-inferiority of palonosetron to another 5-HT_3 antagonist in paediatric patients.	Included on the additional list, specialist use only.	September 2015
panitumumab 20mg/ml concentrate for solution for infusion (Vectibix) *Amgen Ltd* 09.06.08 *SMC Report No. 486/08* NON SUBMISSION Superseded by MTA 242 January 2012	NOT RECOMMENDED: panitumumab (Vectibix) is not recommended as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS (Kirsten rat sarcoma 2 viral oncogene homologue) after failure of fluoropyrimidine -, oxaliplatin -, and irinotecan - containing chemotherapy regimens. 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. MTA 242 Panitumumab monotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.	NOT RECOMMENDED	
panitumumab (Vectibix®) 20 mg/ml concentrate for solution for infusion *Amgen Ltd* 13.02.12 *SMC Report No. 769/12* NON SUBMISSION	NOT RECOMMENDED: panitumumab (Vectibix®) is not recommended for use within NHS Scotland for the treatment of patients with wild-type KRAS metastatic colorectal cancer (mCRC) in first-line in combination with FOLFOX; in second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan). 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	
panitumumab (Vectibix®) *Amgen Ltd* 13.07.15 *SMC Report No. 1082/15* NON SUBMISSION	NOT RECOMMENDED: panitumumab (Vectibix®) is not recommended for use within NHS Scotland. Indication under review: Treatment of adult patients with wild-type RAS metastatic colorectal cancer first-line in combination with FOLFIRI. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of panitumumab in this indication. However, due to the significant time interval between product availability and the expected date of NICE guidance, not recommended advice has been issued.	NOT RECOMMENDED	

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**
panobinostat, 10mg, 15mg and 20mg hard capsules (Farydak®) *Novartis Europharm Limited* 08.02.16 *SMC No. 1122/16* Patient Access Scheme	Accepted use: panobinostat (Farydak®) is accepted for use within NHS Scotland. Indication under review: In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent. In patients with relapsed or relapsed and refractory multiple myeloma, panobinostat in combination with bortezomib plus dexamethasone was associated with a significant benefit in progression-free survival (PFS) compared with bortezomib plus dexamethasone. The treatment effect of the panobinostat containing regimen on PFS was greater in the subgroup of patients' representative of the licensed indication. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of panobinostat. 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, for Specialist Use only, for the indication in question.	July 2016
pasireotide (as pamoate), 20mg, 40mg 60mg powder and solvent for suspension for injection (Signifor®) *Novartis Pharmaceuticals UK Ltd.* 07.09.15 *SMC Report No. 1048/15*	Accepted: pasireotide (as pamoate) (Signifor®) is accepted for use within NHS Scotland. Indication under review: Treatment of adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue. Pasireotide administered every four weeks was significantly superior to an active control group (comprising other somatostatin analogues administered monthly) for the primary endpoint of biochemical control, in patients with inadequately controlled acromegaly following treatment with a somatostatin analogue for at least six months. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the LJF as a prescribing note for the indication in question.	October 2015
pazopanib 200mg, 400mg film-coated tablets (Votrient®) *GlaxoSmithKline UK* 07.03.11 *SMC Report No. 676/11*	Restricted use: pazopanib (Votrient®) is accepted for restricted use within NHS Scotland. Indication under review: First-line treatment of advanced renal cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease. SMC restriction: use is restricted to the first-line treatment of advanced RCC. Pazopanib was superior to placebo for the primary endpoint, progression free survival, in the whole population and the treatment naïve and cytokine pre-treated sub-groups. An indirect comparison demonstrated that pazopanib had similar efficacy to the main comparator. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pazopanib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	Added to the Additional List, for Specialist Use only.	September 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
pazopanib 200mg, 400mg film-coated tablets (Votrient®) *GlaxoSmithKline UK* 10.12.12 *SMC Report No. 820/12*	NOT RECOMMENDED: pazopanib (Votrient®) is not recommended for use within NHS Scotland for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. Efficacy and safety has only been established in certain STS histological tumour subtypes. In a pivotal study, pazopanib significantly improved progression-free survival compared with placebo in adult patients with selective subtypes of advanced STS. However there was no significant improvement in overall survival. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC, and in addition the submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
PCV – procarbazine 50mg capsules, lomustine (CCNU) "medac" 40mg capsules and vincristine sulphate 1mg/mL injection vials / pre-filled infusion Local formulary process	As adjuvant treatment for patients with grade II glioma following radiotherapy. 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2017
pegaspargase (Oncaspar®) 750U/mL solution for injection/infusion *Baxalta* 07.11.16 *SMC Report No. 1197/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: pegaspargase (Oncaspar®) is accepted for use within NHS Scotland as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients. Pegaspargase (Oncaspar®) has been used in NHS Scotland as an unlicensed medicine for the treatment of ALL in children and adults; it has now been granted a product license.	Included on the LJF as first choice, Specialist Use only, for the indication in question.	November 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
pegylated liposomal doxorubicin hydrochloride (PLDH) (Caelyx®) in combination with carboplatin *Janssen – Cilag* 27.04.16 *NICE MTA 389*	NICE (Multiple) Technology Appraisal Guidance No 389 'Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer'. Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer. PLDH in combination with platinum is recommended as an option for treating recurrent ovarian cancer. trabectedin in combination with PLDH is not recommended within their marketing authorisations for treating the first recurrence of platinum-sensitive ovarian cancer The Appraisal Committee was unable to make recommendations on the use of these technologies for treating platinum-sensitive ovarian cancer beyond the first recurrence. The recommendations replace the recommendations in NICE MTA 91 relating to the use of paclitaxel, pegylated liposomal doxorubicin hydrochloride and topotecan for second-line or subsequent treatment of advanced ovarian cancer.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Adiitional List, for Specialist Use only, for the indication in question.	March 2017
pegvisomant 10mg, 15mg, 20mg powder and solvent for injection (Somavert®) *Pfizer Ltd* 12.06.06 *SMC Report No. 158/05* RESUBMISSION	NOT RECOMMENDED: pegvisomant (Somavert®) is not recommended for use within NHS Scotland for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalise insulin-like growth factor 1 (IGF-1) concentrations or was not tolerated. Pegvisomant reduces IGF-1 levels significantly and improves some of the clinical manifestations of acromegaly. It is acknowledged that this is an orphan drug but the economic case has not been demonstrated.	NOT RECOMMENDED	
pegylated liposomal doxorubicin (Caelyx®) *Schering-Plough Ltd* 09.01.04 *SMC Report No. 84/03*	NOT RECOMMENDED: This pegylated liposomal formulation of doxorubicin hydrochloride is now licensed as monotherapy for the treatment of metastatic breast cancer where there is an increased cardiac risk. An inconclusive study has suggested that it was not inferior to conventional doxorubicin in terms of progression-free survival. It was less cardiotoxic than conventional doxorubicin, but was associated with other troublesome adverse events, particularly palmar-plantar erythrodysesthesia. The product is significantly more expensive than the standard preparation and its cost effectiveness in managing metastatic breast cancer has not been addressed by the company in their submission.	NOT RECOMMENDED	
pegylated liposomal doxorubicin, 2mg/ml concentrate for solution for infusion (Caelyx®) *Schering Plough* 13.07.09 *SMC Report No. 503/08* RESUBMISSION	NOT RECOMMENDED: pegylated liposomal doxorubicin (Caelyx®) is not recommended for use within NHS Scotland in combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant. Results from an interim analysis showed that pegylated liposomal doxorubicin plus bortezomib significantly increased the time to disease progression compared to bortezomib monotherapy. At the time of the interim analysis only 31% of patients in the combination arm had reached the primary endpoint. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) *Merck Sharp and Dohme Ltd* 09.11.15 *SMC Report No. 1086/15* Patient Access Scheme	Accepted: pembrolizumab (Keytruda®) is accepted for use within NHS Scotland. Indication under review: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab. In a phase III randomised open-label study, treatment with pembrolizumab (at unlicensed doses) extended median progression free survival and overall survival compared with other immune therapy in patients with advanced melanoma previously untreated with ipilimumab. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. SMC has also assessed pembrolizumab as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults previously treated with ipilimumab and has advised that it is not recommended for use within NHS Scotland in this setting (SMC No.1087/15).	Included on the additional list, Specialist use only, for the indication in question.	April 2016
pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) *Merck Sharp and Dohme Ltd* 12.12.16 *SMC Report No. 1087/15* RESUBMISSION	NOT RECOMMENDED: pembrolizumab (Keytruda®) is not recommended for use within NHS Scotlandas monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously treated with ipilimumab. In a phase II randomised study, pembrolizumab improved progression free survival compared with chemotherapy in patients with advanced melanoma previously treated with ipilimumab and, if BRAF V600 mutant-positive, a BRAF or MEK inhibitor. The submitting company did not present a sufficiently robust economic analysis and in addition its justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	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**
pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) *Merck Sharp and Dohme Ltd* 16.01.17 *SMC Report No. 1204/17* Patient Access Scheme	Restricted use: pembrolizumab (Keytruda®) is accepted for restricted use within NHS Scotland for the treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) and who have received at least one prior chemotherapy regimen. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule. Pembrolizumab, compared with a standard taxane monotherapy, significantly improved overall survival in adults with advanced NSCLC tumours that express PD-L1 and have progressed after platinum-doublet chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines. Not included on the LJF because clinicians do not support the formulary inclusion.	March 2017
pembrolizumab 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion (Keytruda®) *Merck Sharp and Dohme Ltd* 10.07.17 *SMC Report No. 1239/17* Patient Access Scheme	As monotherapy for the first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) with a≥50% tumour proportion score (TPS) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) positive tumour mutations. SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.	Formulary classification not yet decided – waiting for information from clinicans.	
pemetrexed (Alimta®) *Eli Lilly and Company Limited* 08.05.06 *SMC Report No. 268/06* NON SUBMISSION	NOT RECOMMENDED: pemetrexed (Alimta®) is not recommended for use within NHS Scotland as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy. 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	
pemetrexed, 500mg vial of powder for solution for intravenous infusion (Alimta®) *Eli Lilly and Company Limited* 08.09.08 *SMC Report No. 342/07* 2ND RESUBMISSION	Restricted use: pemetrexed (Alimta®) is accepted for restricted use within NHS Scotland for monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. It is restricted to use in patients with good performance status who would otherwise be eligible for treatment with docetaxel. In a retrospective unplanned sub-group analysis of a study comparing pemetrexed with another agent used in the second line treatment of NSCLC, treatment with pemetrexed resulted in an additional median survival of 1.3 months in patients with a non-squamous histology.	Added to the Additional List, for Specialist Use only.	July 2009

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
pemetrexed, 100mg, 500mg powder for concentrate for solution for infusion (Alimta®) *Eli Lilly and Company Limited* 08.02.10 *SMC Report No. 531/09* 2ND RESUBMISSION	Restricted use: pemetrexed (Alimta®) is accepted for restricted use within NHS Scotland in combination with cisplatin for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. It is restricted to patients in whom histology has been confirmed as adenocarcinoma or large cell carcinoma. In a planned subgroup analysis of a study comparing pemetrexed plus cisplatin with another platinum-based combination regimen, treatment with pemetrexed plus cisplatin resulted in an improvement in median survival in patients with a non-squamous (adenocarcinoma plus large cell carcinoma) histology.	Add to the Additional List, for Specialist Use only as first-line treatment	July 2010
pemetrexed 500mg infusion (Alimta®) *Eli Lilly* 05.08.05 *SMC Report No. 192/05*	Restricted use: pemetrexed (Alimta®) in combination with cisplatin is accepted for restricted use within NHS Scotland for the treatment of chemotherapy-naïve patients with stage III/IV unresectable malignant pleural mesothelioma. Pemetrexed in combination with cisplatin prolonged survival compared with cisplatin alone in patients with unresectable malignant pleural mesothelioma. Pemetrexed is the first licensed agent for the treatment of malignant pleural mesothelioma. Pemetrexed is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy. SMC has not yet received a submission for this indication and therefore cannot currently recommend its use.	Added to the Additional List, for Specialist Use only.	August 2005
pemetrexed, 100mg, 500mg powder for concentrate for solution for infusion (Alimta®) *Eli Lilly* 11.10.10 *SMC Report No. 642/10*	NOT RECOMMENDED: pemetrexed (Alimta®) is not recommended for use within NHS Scotland. Indication under review: monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First-line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel. In a sub-group analysis of patients with non-squamous NSCLC, progression free survival and overall survival (secondary endpoint) were significantly longer for pemetrexed plus best supportive care (BSC) compared to placebo plus BSC. However, the manufacturer did not present a sufficiently robust economic case and their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	
pemetrexed, 100mg & 500mg, powder for concentrate for solution for infusion (Alimta®) *Eli Lilly and Company Limited* 08.12.14 *SMC Report No. 770/12*	Accepted for use: pemetrexed (Alimta®) is accepted for use within NHS Scotland as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. In patients with locally advanced or metastatic non-squamous non-small cell lung cancer, maintenance treatment with pemetrexed, following completion of first-line platinum-based chemotherapy, was associated with prolonged overall survival and progression-free survival when compared with placebo. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	January 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**
pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta®) *Roche Products Limited* 12.06.17 *SMC Report No. 897/13* 2nd RESUBMISSION	For use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.	Not routinely available as not recommended for use in NHSScotland.	May 2017
pertuzumab 420mg concentrate for solution for infusion (Perjeta®) *Roche Products Limited* 12.12.16 *SMC Report No. 1121/16* RESUBMISSION	NOT RECOMMENDED: pertuzumab (Perjeta®) is not recommended for use within NHS Scotland for use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence. In a phase II study conducted in women with locally advanced, inflammatory, or early HER2-positive breast cancer, in the neoadjuvant setting, the addition of pertuzumab to trastuzumab plus chemotherapy resulted in a significantly higher proportion of patients achieving pathological complete response in the breast. The submitting 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	
pixantrone (Pixuvri®) 29 mg power for concentrate for solution for infusion *CTI Life Sciences Ltd* 08.02.16 *SMC Report No. 1138/16* NON SUBMISSION	NOT RECOMMENDED: pixantrone (Pixuvri®) is not recommended for use within NHS Scotland. Indication under review: As monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non Hodgkin B-cell Lymphomas. 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	
plerixafor, 20mg/ml solution for injection (Mozobil®) *Genzyme Therapeutics Ltd.* 18.01.10 *SMC Report No. 594/09*	Accepted for use: plerixafor (Mozobil®) is accepted for use within NHSScotland in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly. Significantly more patients treated with plerixafor than with placebo achieved their target collection of CD 34+ cells required for autologous stem cell transplantation with subsequent sustained engraftment.	Added to the Additional List, for Specialist Use only.	August 2010

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) *Celgene Ltd* 08.12.14 *SMC Report No. 972/14* RESUBMISSION Patient Access Scheme	Accepted for use: pomalidomide (Imnovid®) is accepted for use within NHS Scotland in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Pomalidomide plus dexamethasone significantly increased progression-free survival compared with high-dose dexamethasone in patients with refractory or relapsed and refractory multiple myeloma. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pomalidomide. 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.	Included on the Additional List, for Specialist Use only, for the indication in question.	January 2015
ponatinib 15mg, 45mg film-coated tablets (Iclusig®) *ARIAD pharmaceuticals, Inc.* 13.04.15 *SMC Report No.1032/15*	Accepted for use: ponatinib (Iclusig®) is accepted for use within NHS Scotland for adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. Or adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. A non-comparative phase II study of ponatinib was conducted with primary outcomes of major cytogenetic response in patients with baseline chronic phase CML and major haematologic response in patients with baseline accelerated or blast phase CML or Ph+ALL. Ponatinib demonstrated efficacy in heavily pre-treated CML and Ph+ALL patients who had received dasatinib/nilotinib as second line or further line tyrosine kinase inhibitor therapy or who had the T315I mutation. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, specialist use only, for the indication in question.	July 2015

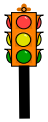
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
posaconazole 100mg gastro-resistant tablets (Noxafil®) *MSD Limited* 13.10.14 *SMC Report No.999/14* PRODUCT UPDATE abbreviated submission)	Restricted use: posaconazole tablets (Noxafil®) is accepted for restricted use within NHS Scotland in the treatment of the following fungal infections in adults: • Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; • Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; • Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; • Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. for prophylaxis of invasive fungal infections in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; • Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections. SMC restriction: to patients in whom there is a specific risk of Aspergillus infection or where fluconazole or itraconazole are not tolerated on the advice of local microbiologists or specialists in infectious diseases. Posaconazole plasma concentrations are generally higher following administration of posaconazole tablets than posaconazole oral suspension. The tablet and oral suspension are therefore not to be used interchangeably. While the tablets are cost saving when administered for treatment they are significantly more expensive than the oral suspension when administered for prophylaxis.	Included on the LJF, for Specialist Use only, for the use in immunocompromised patients for prophylaxis of invasive fungal infections.	October 2014
rabbit anti-human thymocyte immunoglobulin, 25mg powder for solution for infusion (Thymoglobuline®) *Genzyme Therapeutics Ltd* 11.08.08 *SMC Report No. 489/08*	NOT RECOMMENDED: rabbit anti-human thymocyte immunoglobulin, 25mg powder for solution for infusion (Thymoglobuline®) is not recommended for use within NHS Scotland for prevention of graft rejection in renal transplantation. Compared with an alternative agent for induction of immunosuppression it was associated with a lower rate of acute rejection but this did not translate into improved patient or graft survival within the 12-month study period. The manufacturer has not presented a sufficiently robust economic analysis to gain acceptance by SMC. Rabbit anti-human thymocyte immunoglobulin is also licensed for the treatment of steroid resistant graft rejection in renal transplantation and for the prevention of graft rejection in heart transplantation. The manufacturer's submission related only to the prevention of graft rejection in renal transplantation. SMC cannot recommend the use of rabbit anti-human thymocyte immunoglobulin for these additional indications.	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**
radium-223 dichloride 1000kBq/mL solution for injection (Xofigo®) *Bayer Pharma AG* 12.10.15 *SMC Report No. 1077/15* Patient Access Scheme	Accepted: radium-223 dichloride (Xofigo®) is accepted for use within NHS Scotland. Indication under review: for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. In a randomised phase III study of adult men with castration-resistant prostate cancer with symptomatic bone metastases and no known visceral metastases, treatment with radium-223 dichloride was associated with a significant improvement in overall survival compared to placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of radium-223 dichloride. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2015
ramucirumab (Cyrmaza®) 10 mg/mL concentrate for solution for infusion *Eli Lilly and Company Limited* 09.05.16 *SMC Report No. 1156/16* NON SUBMISSION	NOT RECOMMENDED: ramucirumab (Cyramza®) is not recommended for use within NHS Scotland. Indication under review: in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) for the treatment of adult patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. 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	
ramucirumab (Cyrmaza®) 10 mg/mL concentrate for solution for infusion *Eli Lilly and Company Limited* 13.06.16 *SMC Report No. 1165/16* NON SUBMISSION	NOT RECOMMENDED: ramucirumab (Cyramza®) is not recommended for use within NHS Scotland in combination with docetaxel for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy. 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**
ramucirumab (Cyramza®) 10 mg/mL concentrate for solution for infusion *Eli Lilly and Company Limited* 11.07.16 *SMC Report No. 1176/16* NON SUBMISSION	NOT RECOMMENDED: ramucirumab (Cyramza®) is not recommended for use within NHS Scotland. Indications under review: • In combination with paclitaxel for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy • As monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate The holder of the marketing authorisation has not made a submission to SMC regarding this product in these indications. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
regorafenib 40mg film-coated tablet (Stivarga®) *Bayer plc* 13.04.15 *SMC Report No. 1031/15* Patient Access Scheme	Accepted for use: regorafenib (Stivarga®) is accepted for use within NHS Scotland as treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib. In a study of patients with metastatic or unresectable GIST who had prior treatment with imatinib and sunitinib, treatment with regorafenib prolonged the median progression free survival by 3.9 months when compared with placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of regorafenib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only, for the indication in question.	May 2015
regorafenib (Stivarga®) 40mg film-coated tablets *Bayer Plc* 09.11.15 *SMC Report No. 1118/15* NON SUBMISSION	NOT RECOMMENDED: regorafenib (Stivarga®) is not recommended for use within NHS Scotland. Indication under review: Adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies 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	
rituximab (MabThera®) *Roche* 07.03.03 *SMC Report No. 33/03*	Restricted use: rituximab is recommended for use by oncologists or haematologists in Scotland who have expertise in treating lymphoma. It should be administered in a hospital environment where full resuscitation facilities are available.	Added to the Formulary as a Prescribing Note, for Specialist Use only.	September 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**
rituximab (MabThera®) *Roche* 13.12.04 *SMC Report No. 135/04*	Accepted for use: rituximab is accepted for use within NHS Scotland for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with cyclophosphamide, vincristine and prednisolone (CVP) chemotherapy. Rituximab is for use only by oncologists or haematologists who have expertise in treating lymphoma. It should be administered in a hospital environment where full resuscitation facilities are available. Limited results show that rituximab plus CVP significantly increased the time to treatment failure compared with CVP alone.	Added to the Formulary as a Prescribing Note, for Specialist Use only.	March 2005
rituximab 10mg/mL concentrate for infusion (MabThera®) *Roche* 11.12.06 *SMC Report No. 330/06*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland as maintenance therapy for patients with relapsed/refractory follicular lymphoma responding to induction therapy with chemotherapy with or without rituximab. In a phase lll, randomised, open-label study, rituximab maintenance treatment significantly increased the median progression-free survival from 15 months in the observation arm to 52 months in the rituximab arm with an increase in overall survival at three years. This prolonged survival requires to be confirmed in longer term follow up. Rituximab is restricted for use only by oncologists or haematologists who have expertise in treating lymphoma.	Added to the Additional List, for Specialist Use only.	May 2007
rituximab, 100mg and 500mg concentrate for solution for infusion (MabThera®) *Roche* 08.09.08 *SMC Report No. 493/08*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland for the treatment of previously untreated patients with stage III to IV follicular lymphoma in combination with chemotherapy. Rituximab added to a number of different chemotherapy regimens produced statistically significant improvements in the primary study endpoints when compared with the chemotherapy regimens alone. Rituximab is restricted to use only by haematologists or oncologists who have expertise in treating lymphoma. It should be administered in a healthcare environment where full resuscitation facilities are available. SMC issued advice in December 2004 regarding the use of rituximab in combination with cyclophosphamide, vincristine and prednisolone (CVP) chemotherapy for the treatment of previously untreated patients with stage III to IV follicular lymphoma. The current advice extends the range of chemotherapy regimens that can be used in combination with rituximab for this indication.	Added to the Additional List, for Specialist Use only.	March 2011
rituximab, 100mg and 500mg concentrate for solution for infusion (MabThera®) *Roche* 08.06.09 *SMC Report No. 540/09*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland for first-line treatment of patients with chronic lymphocytic leukaemia (CLL) in combination with fludarabine and cyclophosphamide. Rituximab in combination with fludarabine and cyclophosphamide resulted in significantly longer progression free survival than fludarabine and cyclophosphamide alone. The patient population in the pivotal clinical study had an Eastern Cooperative Oncology Group Performance Status of 0 or 1 and was a younger population than that generally seen in practice. Evidence in patients over 70 years of age is limited. Rituximab is restricted to use by specialists in haematology and haemato-oncology.	Added to the Additional List, for Specialist Use only.	December 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**
rituximab, 100mg and 500mg concentrate for solution for infusion (MabThera®) *Roche* 18.01.10 *SMC Report No. 591/09*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland. Licensed indication under review: for the treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia (CLL) in combination with chemotherapy. Rituximab in combination with fludarabine and cyclophosphamide resulted in significantly longer progression-free survival than fludarabine and cyclophosphamide alone. The patient population in the pivotal clinical study had an Eastern Cooperative Oncology Group Performance Status of 0 or 1 and was a younger population than that generally seen in clinical practice. Evidence in patients over 70 years of age is limited. Restriction: Rituximab is restricted to use by specialists in haematology and haemato-oncology.	Added to the Additional List, Specialist Use only.	April 2011
rituximab, 100mg in 10mL, 500mg in 50mL, concentrate for solution for infusion (MabThera®) *Roche Products Limited* 07.02.11 *SMC Report No. 675/11*	Restricted use: rituximab (MabThera®) is accepted for restricted use within NHS Scotland. Indication under review: Rituximab maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. SMC restriction: for maintenance treatment in follicular lymphoma patients who have responded to induction with rituximab plus chemotherapy. Rituximab significantly increased progression free survival following a response to induction therapy in patients with previously untreated follicular lymphoma compared with observation alone. Longer follow up is required to establish benefit in overall survival.	Added to the Additional List, for Specialist Use only.	March 2011
rituximab (Mabthera®) *Roche*	In combination with bendamustine for first-line treatment of Chronic Lymphocytic Leukaemia.	Added to the Additional List, for Specialist Use only.	April 2014

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
rituximab 1400mg solution for subcutaneous injection (Mabthera®) *Roche Products Limited* 07.07.14 *SMC Report No. 975/14* Patient Access Scheme	Restricted use: rituximab subcutaneous injection (Mabthera®) is accepted for restricted use within NHS Scotland for non-Hodgkin's lymphoma (NHL) in adults: - previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy; - maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy; - treatment of patients with CD20 positive diffuse large B cell - non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy. SMC restriction: Subcutaneous rituximab is accepted for use in line with previous SMC advice for intravenous rituximab i.e. accepted within licensed indication as above except in the maintenance setting, where use is restricted to patients who have responded to induction therapy with rituximab plus chemotherapy. In two pharmacokinetic-based clinical bridging studies, rituximab subcutaneous injection was shown to be non inferior to rituximab intravenous infusion for trough concentration and area under the concentration time curve. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of rituximab subcutaneous injection. 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, Specialist Use only, for the indication in question.	October 2014
rituximab, methotrexate, cytarabine and thiotepa (MATRIX) Local formulary process	Treatment of central nervous system lymphoma. 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2017

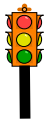
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
rolapitant (as hydrochloride monohydrate 90mg film-coated tablets (Varuby®) Tesaro UK Limited 11.09.17 *SMC Report No 1266/17* *Patient Access Scheme*	Accepted for restricted use within NHS Scotland. Indication under review: Prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. Rolapitant is given as part of combination therapy. SMC restriction: as a first-line option in adults undergoing highly emetogenic chemotherapy (HEC). In phase III studies of patients scheduled to receive highly or moderately emetogenic chemotherapy, a greater proportion of patients treated with rolapitant-based combination therapy achieved a complete response (defined as no emesis or use of rescue medication) in the delayed phase (>24 to 120 hours after initiation of chemotherapy) of cycle one compared with combination therapy alone. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of rolapitant. 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.	
ruxolitinib (Jakavi®) 5mg, 15mg and 20mg Tablets *Novartis Pharmaceuticals UK Ltd* 09.03.15 *SMC Report No. 867/13* *Patient Access Scheme*	Accepted for use: ruxolitinib (Jakavi®) 5mg, 15mg and 20mg Tablets is accepted for use within NHS Scotland as the the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. In patients with myelofibrosis, a significantly greater proportion of patients achieved a spleen response (reduction in spleen volume of at least 35% from baseline) at 48 weeks when treated with ruxolitinib compared with best available therapy. Ruxolitinib was also associated with a greater proportion of patients reporting a clinically significant reduction in myelofibrosis-related symptoms when compared with placebo. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of ruxolitinib. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2015
ruxolitinib phosphate (Jakavi®) 5mg, 10mg, 15mg and 20mg tablets *Novartis Pharmaceuticals UK Ltd* 13.06.16 *SMC Report No. 1166/16* NON SUBMISSION	NOT RECOMMENDED: ruxolitinib phosphate (Jakavi®) is not recommended for use within NHS Scotland for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. 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**
sorafenib 200mg tablets (Nexavar®) *Bayer Plc* 13.11.06 *SMC Report No. 321/06*	NOT RECOMMENDED: sorafenib (Nexavar®) is not recommended for use within NHS Scotland for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alfa or interleukin-2 based therapy or are considered unsuitable for such therapy. Sorafenib has been compared with best supportive care and has been shown to increase progression-free survival, though the impact on overall survival is uncertain. The cost effectiveness of sorafenib has not been demonstrated.	NOT RECOMMENDED	
sorafenib 200mg film-coated tablets (Nexavar®) *Bayer Plc.* 13.07.15 *SMC Report No. 1055/15* Patient Access Scheme	Accepted for use: sorafenib (Nexavar®) is accepted for use within NHS Scotland. Indication under review: treatment of patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine. Treatment with sorafenib demonstrated a significant, clinically relevant five-month improvement in median progression free survival compared with placebo in patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sorafenib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, Specialist Use only.	September 2015
sorafenib 200mg film-coated tablets (Nexavar®) *Bayer plc* 11.01.16 *SMC Report No. 482/08* 2nd RESUBMISSION Patient Access Scheme	Restricted use: sorafenib (Nexavar®) is accepted for restricted use within NHS Scotland. Indication under review: the treatment of hepatocellular carcinoma. SMC restriction: in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies. In a phase III study in patients with advanced hepatocellular carcinoma, sorafenib was superior to placebo in terms of overall survival, but not for time to symptomatic progression. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sorafenib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the additional list, Specialist use only, for the indication in question.	April 2016
sunitinib 12.5mg, 25mg, 50mg capsules (Sutent®) *Pfizer Ltd* March 2009 *NICE MTA 169* *Supersedes SMC Report No. 384/07*	Sunitinib is recommended as a first-line treatment option for people with advanced and/or metastatic renal cell carcinoma who are suitable for immunotherapy and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.	Added to the Additional List, for Specialist Use only.	July 2010

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
sunitinib 50mg capsule (Sutent®) *Pfizer* 09.11.09 *SMC Report No. 275/06* RESUBMISSION Patient Access Scheme	Accepted for use: Sunitinib (Sutent®) is accepted for use within NHS Scotland for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesilate treatment due to resistance or intolerance. Sunitinib compared with placebo delayed tumour progression by approximately five months. Treatment with sunitinib should not be continued if there is evidence of unacceptable toxicity or progression of disease. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sunitinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Added to the Additional List, for Specialist Use only	July 2010
sunitinib 50mg capsule (Sutent®) *Pfizer* 12.02.07 *SMC Report No. 343/07*	NOT RECOMMENDED: sunitinib (Sutent®) is not recommended for use within NHS Scotland for the treatment of advanced and/or metastatic renal cell carcinoma after failure of interferon-alpha or interleukin-2 therapy. In uncontrolled trials, sunitinib has been associated with tumour responses in patients who have metastatic renal cell cancer. However, the economic case has not been demonstrated.	NOT RECOMMENDED	
sunitinib 12.5mg, 25mg, 37.5mg, 50mg hard capsules (Sutent®) *Pfizer Limited* 09.05.11 *SMC Report No. 698/11* Patient Access Scheme	Accepted for use: sunitinib (Sutent®) is accepted for use within NHS Scotland. Indication under review: Treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults. Treatment with sunitinib improved progression free survival compared with placebo in patients with well-differentiated neuroendocrine carcinoma of the pancreas who were receiving best supportive care, including somatostatin analogues if required for symptomatic control. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sunitinib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	Added to the Additional List, for Specialist use only.	August 2011
tacrolimus, 5mg/ml concentrate for infusion and 0.5mg, 1mg, 5mg hard capsules (Prograf®) *Astellas Pharma Ltd* 12.02.07 *SMC Report No. 346/07*	Restricted use: tacrolimus (Prograf®) is accepted for restricted use within NHS Scotland for the prophylaxis of transplant rejection in heart allograft recipients. It has shown comparable efficacy to ciclosporin-based regimens in prevention of acute rejection. It is restricted to use in patients where ciclosporin is not suitable.	Added to the Additional List, if initiated by specialists working in Heart Transplantation. Shared care for use in Kidney and Liver transplants.	December 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**
tacrolimus 0.5mg, 1mg, 5mg prolonged-release capsule (Advagraf®) *Astellas Pharma* 10.09.07 *SMC Report No. 402/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: tacrolimus prolonged-release capsule (Advagraf®) is accepted for use within NHS Scotland for prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. It is suitable for use by patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy. It has similar costs per equivalent dose to the tacrolimus immediate release capsule.	New formulation of a drug already included in the Formulary.	October 2007
tacrolimus granules for oral suspension (Modigraf®) *Astellas Pharma Ltd* 13.12.10 *SMC Report No. 657/10* PRODUCT UPDATE (abbreviated submission)	Restricted use: tacrolimus granules for Oral Suspension (Modigraf®) are accepted for restricted use within NHS Scotland. Indication under review: • Prophylaxis of transplant rejection in adult and paediatric, kidney, liver or heart allograft recipients. • Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult and paediatric patients. SMC restriction: for use in patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy and where small changes (less than 0.5mg) in dosing increments are required (e.g. in paediatric patients) or seriously ill patients who are unable to swallow tacrolimus capsules. Modigraf® granules for oral suspension offer 18% greater bioavailability than immediate release capsules and may have different bioavailability compared to other unlicensed tacrolimus suspensions in use in the past. Careful monitoring and possible dosage changes are needed when introducing treatment with Modigraf®. Tacrolimus granules for oral suspension are significantly more expensive than the capsule formulation.	Added to the Additional List, for use on the advice of a transplant specialist.	March 2011
tacrolimus (as monohydrate) 0.75mg, 1mg and 4mg prolonged- release tablets (Envarsus®) *Chiesi Ltd* 13.04.15 *SMC Report No.1041/15* PRODUCT UPDATE (abbreviated submission)	Accepted for use: tacrolimus (Envarsus®) prolonged release-tablets are accepted for use within NHS Scotland as prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients. Tacrolimus (Envarsus®) is suitable for use by patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy. It has increased bioavailability compared with other tacrolimus preparations. Tacrolimus (Envarsus®) has demonstrated non-inferiority to a tacrolimus immediate-release capsule and has a similar cost per equivalent dose.	Not included on the LJF because clinicians do not support the formulary inclusion.	April 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**
tegafur/gimeracil/oteracil 15mg/4.35mg/ 11.8mg and 20mg/5.8mg/15.8mg hard capsules (Teysuno®) *Nordic Pharma Ltd.* 10.09.12 *SMC Report No 802/12*	Restricted use: tegafur/gimeracil/oteracil (Teysuno®) is accepted for restricted use within NHS Scotland and is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin. SMC restriction: tegafur/gimeracil/oteracil is restricted to use in patients with advanced gastric cancer who are unsuitable for an anthracycline, fluorouracil and platinum triplet first-line regimen. In a multicentre, randomised, open-label clinical study in adult patients with advanced gastric cancer, tegafur/gimeracil/oteracil in combination with cisplatin was non-inferior to an intravenous fluoropyrimidine plus cisplatin with respect to overall survival.	Not included on the LJF because clinicians do not support the formulary inclusion.	October 2012
talimogene laherparepvec (Imlygic®) 10^6 and 10^8 plaque forming units (PFU)/mL solution for injection *Amgen Ltd* 08.05.17 *SMC Report No. 1248/17* NON SUBMISSION	Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.	Not routinely available as not recommended for use in NHSScotland.	May 2017
temoporfin (Foscan®) *Biolitec Pharma* 10.05.04 *SMC Report No. 96/04*	NOT RECOMMENDED: temoporfin (Foscan®) is not recommended for use within NHS Scotland for the palliative treatment of patients with advanced head and neck squamous cell carcinoma failing prior therapies and unsuitable for radiotherapy, surgery or systemic chemotherapy. It is the first photosensitising drug licensed in the UK for use in photodynamic therapy (PDT) for the treatment of these patients. Its effect in terms of tumour mass reduction and improvement in quality of life were small and were only observed in patients with lesions less than 10mm deep, which were fully illuminated with activating light. The quality of life benefits resulting from palliation, particularly in this subgroup, were marginal and the economic case for its use over other palliative treatments was not made.	NOT RECOMMENDED	
temozolomide 5, 20, 100 and 250mg capsules (Temodal®) *Schering Plough UK Ltd* 11.12.06 *SMC Report No. 244/06* RESUBMISSION.	Restricted use: temozolomide (Temodal®) is accepted for restricted use within NHS Scotland for the treatment of newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and subsequently as monotherapy treatment. In a three-year follow up of the pivotal phase lll study, a significant survival benefit was seen over placebo in patients with good performance status and favourable prognostic markers. Temozolamide is restricted to patients who have had a partial or complete macroscopic resection of their tumour and with World Health Organisation (WHO) performance status 0 or 1.	Added to the LJF as first choice adjuvant treatment in patients with grade IV GBM. For specialist use only,	April 2007
temozolomide 5, 20, 100 and 250mg capsules Local formulary process	Concurrent with intermediate course radiotherapy and adjuvant for patients with newly diagnosed glioblastoma.	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only.	July 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
temozolomide 5, 20, 100 and 250mg capsules Local formulary process	Adjuvant treatment following radiotherapy for patients with grade III glioma without 1p19q co-deletion 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	August 2017
temsirolimus (Torisel®) *Wyeth Pharmaceuticals* 12.04.10 *SMC Report No. 617/10* NON SUBMISSION	NOT RECOMMENDED: temsirolimus (Torisel®) is not recommended for use within NHS Scotland. Licensed indication under review: the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma [MCL]. 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	
thalidomide, 50mg hard capsule (Thalidomide Pharmion®) *Celgene Ltd* 12.01.09 *SMC Report No. 525/08*	Accepted for use: thalidomide (Thalidomide Pharmion®) is accepted for use within NHS Scotland in combination with melphalan and prednisone, as first line treatment of patients with untreated multiple myeloma, aged 65 years or over or ineligible for high dose chemotherapy. Thalidomide is prescribed and dispensed according to the Thalidomide Pharmion Pregnancy Prevention Programme. In the pivotal trial in patients aged 65 to 75 years, at 51.5 months median follow-up, the addition of thalidomide to melphalan and prednisone gave an overall survival advantage of 18.4 months.	Added to the Additional List, for Specialist Use only.	July 2009
thiotepa 15mg and 100mg powder for concentrate for solution for infusion (Tepadina®) *Adienne S.r.l.* 09.07.12 *SMC Report No. 790/12*	NOT RECOMMENDED: thiotepa (Tepadina®) is not recommended for use within NHS Scotland in combination with other chemotherapy medicinal products: 1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients; 2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients. Two uncontrolled, non-randomised studies including patients with advanced non-Hodgkin's lymphoma or Hodgkin's disease have reported data for non-relapse mortality and overall survival. The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	NOT RECOMMENDED	
topotecan (Hycamtin®) *Merck Pharmaceuticals*	Platinum-resistant or refractory ovarian cancer	Added to the Additional List.	September 2005

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**
topotecan 1mg, 4mg powder for concentrate for solution for infusion (Hycamtin®) *GlaxoSmithKline* 07.05.07 *SMC Report No. 366/07*	NOT RECOMMENDED: topotecan (Hycamtin®) is not recommended for use within NHS Scotland for the treatment of patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate. In a trial comparing oral topotecan plus active symptom control (ASC) to ASC alone the difference in median survival was 12 weeks, in favour of the oral topotecan plus ASC group. Topotecan is not available as an oral formulation in the UK, however, in one trial the response rate and median survival duration were similar for oral and IV topotecan groups. The treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	
topotecan 1mg, 4mg powder for concentrate for solution for infusion (Hycamtin®) *GlaxoSmithKline* 10.12.07 *SMC Report No. 421/07*	Restricted use: topotecan (Hycamtin®) is accepted for restricted use within NHS Scotland in combination with cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with stage IVB disease. It is restricted to patients who are cisplatin-naïve. In an open-label study, overall and progression-free survival were significantly longer for cisplatin plus topotecan compared with cisplatin alone. Haematological adverse events were more common in the cisplatin plus topotecan group. The economic submission demonstrated that topotecan plus cisplatin was cost effective compared to cisplatin alone in cisplatin-naïve patients. However, the manufacturer's justification of the treatment's cost in relation to its health benefit was not sufficient to gain acceptance by SMC for use in patients with previous exposure to cisplatin.	Added to the Formulary as recommended by SMC Advice. Not Preferred for use in patients, who have received cisplatin previously (see table on non-SMC drugs).	November 2008
topotecan (Hycamtin®) *GlaxoSmithKline*	Recurrent or metastatic carcinoma cervix	Added to the Formulary as recommended by SMC Advice. Not Preferred for use in patients, who have received cisplatin previously.	November 2008
topotecan 0.25mg, 1mg hard capsules (Hycamtin®) *GlaxoSmithKline* 14.04.09 *SMC Report No. 545/09*	Restricted use: topotecan capsules (Hycamtin®) are accepted for restricted use within NHS Scotland as monotherapy for the treatment of adult patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate. The efficacy of topotecan capsules relative to standard IV chemotherapy is unknown. Topotecan capsules are restricted to use in patients for whom standard intravenous chemotherapy is inappropriate and who would otherwise receive best supportive care. In one study, oral topotecan plus best supportive care (BSC) was superior to BSC alone for the primary endpoint of median survival.	Added to the Additional List, for Specialist Use only.	July 2009

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
trabectedin (Yondelis®) *Pharma Mar SA* 11.07.11 *SMC Report No. 452/08* 2nd RESUBMISSION	NOT RECOMMENDED trabectedin (Yondelis®) is not recommended for use within NHS Scotland. Indication under review: treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. In a phase II randomised study in patients with advanced leiomyosarcoma and liposarcoma in which two trabectedin dose schedules were compared, the licensed 3-weekly schedule was superior to the alternative schedule for the primary endpoint, time to progression. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED	
trabectedin (Yondelis®) *Pharma Mar SA Ltd* 13.09.10 *SMC Report No. 634/10*	NOT RECOMMENDED: trabectedin (Yondelis®) is not recommended for use within NHS Scotland. Indication under review: Trabectedin in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer. In an open-label randomised controlled study trabectedin in combination with PLD was significantly superior to PLD monotherapy in terms of progression free survival. There was a significant difference in an exploratory interim analysis of overall survival in the sub-group of patients with partially platinum-sensitive disease. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and in addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC	NOT RECOMMENDED	
trametinib 0.5mg and 2mg film-coated tablets (Mekinist®) *Novartis Pharmaceuticals UK Ltd* 12.09.16 *SMC Report No. 1161/16* Patient Access Scheme	Restricted use: trametinib (Mekinist®) is accepted for restricted use within NHS Scotland in combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. SMC restriction: to first-line treatment. In two phase III studies, trametinib in combination with dabrafenib improved progression-free survival and overall survival compared with BRAF inhibitor monotherapy for the first-line treatment of unresectable or metastatic melanoma with BRAF V600 mutation in adults. This advice takes account of the benefits of Patient Access Schemes (PAS) that improve the cost-effectiveness of trametinib and dabrafenib. This advice is contingent upon the continuing availability of these patient access schemes in NHS Scotland or list prices that are equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. Trametinib is also licensed as monotherapy. As the company submission related only to combination therapy, SMC cannot recommend use as monotherapy.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 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**
trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) *Novartis Pharmaceuticals UK Limited* 10.07.17 *SMC Report No. 1264/17* NON SUBMISSION	NOT RECOMMENDED: In combination with dabrafenib for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation.	Not routinely available as not recommended for us in NHSScotland.	July 2017
trastuzumab (Herceptin®) *Roche Pharmaceuticals* 09.07.07 *SMC Report No. 386/07* NON SUBMISSION	NOT RECOMMENDED: trastuzumab (Herceptin®) in combination with an aromatase inhibitor is not recommended for metastatic breast cancer. 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	
trastuzumab 150mg vial (Herceptin®) *Roche* 09.06.06 *SMC Report No. 278/06*	Restricted use: trastuzumab (Herceptin®) is accepted for restricted use within NHSScotland for the treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). In the pivotal trial, the addition of one year of 3-weekly trastuzumab after adjuvant chemotherapy significantly increased disease-free survival compared with that in the observation group. The trial excluded patients with a range of cardiovascular conditions and trastuzumab treatment for early breast cancer is not recommended in such patients. In patients treated with trastuzumab for early breast cancer, monitoring of cardiac function is required before treatment, every three months during treatment and for up to two years after treatment has stopped. Trastuzumab in this indication is restricted to use by breast cancer specialists.	Added to LJF as first choice for use in patients with HER2 positive early breast cancer following surgery, chemotherapy and radiotherapy (if applicable). For specialist use only.	April 2007
trastuzumab, 150mg powder for concentrate for solution for infusion (Herceptin®) *Roche Products Ltd.* 12.10.15 *SMC Report No. 623/10* 2nd RESUBMISSION	Restricted use: trastuzumab (Herceptin®) is accepted for restricted use within NHS Scotland. Indication under review: in combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. It is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay. SMC restriction: for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser"). The addition of trastuzumab to doublet chemotherapy improved overall and progression-free survival and tumour response. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List, for Specialist Use only, 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**
trastuzumab, 600mg/5mL solution for injection (Herceptin®) *Roche Products Ltd* 13.01.14 *SMC Report No. 828/13*	Restricted use: trastuzumab 600mg/5mL solution for injection (Herceptin®) is accepted for restricted use within NHS Scotland for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (full details of licensed indication presented later in advice document). Trastuzumab should only be used in patients with metastatic or early breast cancer whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. SMC restriction: Subcutaneous trastuzumab injection is accepted for use in line with previous SMC advice for intravenous trastuzumab (this excludes its use in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab). In a phase III randomised, open-label clinical study in patients with HER2-positive early breast cancer, subcutaneous trastuzumab was non-inferior to intravenous trastuzumab for the co-primary pharmacokinetic and efficacy endpoints of serum trough concentration (C_{trough}) at pre-dose cycle 8 before surgery and pathological complete response.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2014
trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla®) *Roche Products Ltd.* 10.04.17 *SMC Report No. 990/14* RESUBMISSION Patient Access Scheme	As a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for locally advanced or metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
trifluridine/tipiracil (as hydrochloride), 15mg/6.14mg and 20mg/8.19mg film-coated tablets (Lonsurf®) *Servier Laboratories Limited* 13.02.17 *SMC Report No. 1221/17* Patient Access Scheme	Accepted for use: trifluridine/tipiracil (Lonsurf®) is accepted for use within NHS Scotland for the treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents, and anti-epidermal growth factor receptor agents. Treatment with trifluridine/tipiracil was associated with an improvement in overall survival when compared with best supportive care in patients who had received, or were intolerant of, first and second-line therapies for metastatic CRC. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of trifluridine/tipiracil. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	April 2017
triptorelin 3.75mg (Gonapeptyl Depot®) *Ferring Pharmaceuticals Ltd* 08.05.06 *SMC Report No. 269/06* NON SUBMISSION	NOT RECOMMENDED: Gonapeptyl Depot® is not recommended for use within NHSScotland for the treatment of advanced, hormone-dependent prostate carcinoma. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
triptorelin acetate (Decapeptyl® SR 11.25mg) *Ipsen Ltd* 12.07.04 *SMC Report No. 109/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Decapeptyl® SR 11.25mg is accepted for use within NHS Scotland for the treatment of advanced prostate cancer in patients for whom the use of triptorelin is appropriate and who would benefit from reduced frequency of administration compared with Decapeptyl® SR 3mg (every 3 months vs every 28 days).	Added to the Formulary as first choice gonadorelin analogue for advanced prostate cancer instead of goserelin or leuprorelin.	May 2005
triptorelin (Decapeptyl SR®) 22.5mg powder and solvent for suspension for injection *Ipsen Ltd* 13.06.11 *SMC Report No. 705/11* PRODUCT UPDATE (abbreviated submission)	Accepted for use: triptorelin pamoate 22.5mg (Decapeptyl SR®) is accepted for use within NHS Scotland. • Treatment of patients with locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration. • Treatment of metastatic prostate cancer. This new preparation of triptorelin allows 6-monthly administration (as triptorelin pamoate in a 22.5mg dose). Triptorelin 11.25mg (as acetate) is administered every 3 months and has previously been accepted by SMC. Bioequivalence of the pamoate and acetate salts has been demonstrated and the new preparation is cost neutral. Note: The indication for triptorelin 11.25mg formulation was reworded in 2007 to achieve consistency Europe-wide and now reads as per the indication for triptorelin 22.5mg.	Added to the Formulary, as a new formulation of a product already included.	May 2011

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
vandetanib (Caprelsa®) 100 mg / 300mg film coated tablets *AstraZeneca UK Limited* 11.06.12 *SMC Report No. 797/12* NON SUBMISSION	NOT RECOMMENDED: vandetanib (Caprelsa®) is not recommended for use within NHS Scotland for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. 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	
vemurafenib 240mg film-coated tablet (Zelboraf®) *Roche Products Ltd.* 09.12.13 *SMC Report No. 792/12* RESUBMISSION Patient Access Scheme	Restricted use: vemurafenib (Zelboraf®) is accepted for restricted use within NHS Scotland as monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. SMC restriction: for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma. Vemurafenib significantly increases overall survival and progression-free survival compared with a current standard chemotherapy for patients with previously untreated unresectable stage IIIC or stage IV melanoma with V600 BRAF mutation. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of vemurafenib. 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.	February 2014
venetoclax 10mg, 50mg and 100mg film-coated tablets (Venclyxto®) *AbbVie Ltd* 07.08.17 *SMC Report No. 1249/17* Patient Access Scheme	As monotherapy for the treatment of chronic lymphocytic leukaemia (CLL): • in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor. • in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.	Formulary classification not yet decided – waiting for information from clinicans.	
vinorelbine 20 and 30mg capsules (Navelbine® Oral) *Pierre Fabre Ltd* 13.06.05 *SMC Report No. 179/05*	Restricted use: vinorelbine capsule (Navelbine®Oral) is accepted for restricted use within NHS Scotland for the first line treatment of stage lll or lV non-small-cell lung cancer. It is restricted to use by specialist oncologists as an alternative to the intravenous formulation of vinorelbine. It is more expensive than the intravenous formulation of vinorelbine. However, its use may allow changes to service delivery that have individual patient or organisational benefits.	'Not preferred' in Lothian.	July 2007

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
vinorelbine 20mg and 30mg capsule (Navelbine®) *Pierre Fabre Ltd* 13.08.07 *SMC Report No. 324/06* PRODUCT UPDATE (abbreviated submission)	Restricted use: Vinorelbine capsule (Navelbine®) is accepted for restricted use within NHS Scotland for treatment of advanced breast cancer stage III and IV relapsing after, or refractory to, an anthracycline-containing regimen. It is restricted to use by specialist oncologists as an alternative to the intravenous formulation of vinorelbine where vinorelbine is considered to be appropriate. It is more expensive than the intravenous formulation of vinorelbine. However, its use may allow changes to service delivery that have individual patient or organisational benefits.	Added to the Additional List, for Specialist Use only.	July 2008
vismodegib (Erivedge®) 150 mg hard capsules *Roche Products Ltd* 07.10.13 *SMC Report No. 924/13* NON SUBMISSION	NOT RECOMMENDED: vismodegib (Erivdege®) is not recommended for use within NHS Scotland for the treatment of adult patients with: • symptomatic metastatic basal cell carcinoma • locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy 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	
Zarzio filgrastim 300mcg and 480mcg pre-filled syringes Local formulary process	For primary or secondary prophylaxis of neutropenia; treatment of profound neutropenia associated with sepsis and mobilisation of autologous stem cells for transplants.	Routinely available in line with local or regional guidance. Included on the LJF as a first choice, for Specialist initiation.	May 2017
zoledronic acid (Zometa®) *Novartis Europharm Ltd* 12.05.03 *SMC Report No. 29/02* Resubmission	Restricted use: zoledronic acid (Zometa®) should be restricted to prescribing by oncologists for patients with breast cancer and multiple myeloma. It provides an alternative to other bisphosphonates licensed for prevention of skeletal related events. It may offer some minor advantages in terms of administration. At a local level the decision will rest on weighing up the additional cost against other options available for improving the delivery of oncology services. Zoledronic acid has a broader range of indications than other bisphosphonates available and has shown some efficacy in patients with prostate cancer and NSCLC and other solid tumours. The quality of the economic evidence provided is insufficient to demonstrate that the use of this product for these indications is cost effective. The licence holder has indicated their decision to appeal.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	
zoledronic acid (Zometa®) *Novartis Europharm Ltd* 12.01.04 *SMC Report No. 29/02* FOLLOWING INDEPENDENT REVIEW PANEL ASSESSMENT	NOT RECOMMENDED: zoledronic acid (Zometa®) is not recommended for use within NHS Scotland for the prevention of skeletal related events (SREs) in patients with advanced prostate cancer involving bone. Although zoledronic acid demonstrated a reduction in SREs compared with placebo in these patients, the absolute reduction was small and the study requires caution in accepting this as sufficient evidence to introduce zoledronic acid into standard practice for the treatment of patients with metastatic prostate cancer. An economic case was submitted by the manufacturer but its quality was not judged to be sufficient to support a recommendation that the drug is cost effective relative to standard practice in Scotland for this particular indication.	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**
zoledronic acid (Zometa®) *Novartis*	For tumour induced hypercalcaemia	Added to the Formulary as first choice. To be included in the section for tumour induced hypercalcaemia.	April 2010
zoledronic acid (Zerlinda®) 4mg/100mL solution for infusion pre-filled bag *Actavis*	Adjuvant use in women at high risk of recurrence to reduce the rate of breast cancer recurrence in bone.  High risk patients are: • breast cancer patients (irrespective of whehter they have had chemotherapy) who are post-menopausal and deemed by local protocol to be high risk: i.e. ER low/negative, or ER 4-8 with one or more of the following features – HER2 positive or Grade 3 or T3/4 or node positive. • pre-menopausel patients in the same risk category who warrant ovarian suppression.	Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	October 2016
zoledronic acid (Zerlinda®) 4mg/100mL solution for infusion *Actavis* Local formulary process	Prevention of skeletal related events in patients with skeletal metastases from solid tumours excluding breast and prostate cancer.	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only	August 2017