NEW DRUG RECOMMENDATIONS
DECEMBER 2011

NHS Greater Glasgow and Clyde

Section 1: Medicines accepted by SMC – Major Changes to Formulary

Medicine name:	Mifamurtide (Mepact®) *Takeda UK and Ireland Ltd*	Reason for consideration:	New medicine
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.		
SMC/ HIS reference:	SMC 621/10 [Resubmission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Add to Total Formulary Restricted to use in accordance with regional protocol.		✓R
ADTC Decision 12/12/11	AGREED		

Medicine name:	Bendamustine hydrochloride (Levact®) *Napp Pharmaceuticals Ltd*	Reason for consideration:	New medicine
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.		
SMC/ HIS reference:	SMC 694/11 [Deferred Decision]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Add to Total Formulary Restricted to use in accordance with regional protocol.		✓R
ADTC Decision 12/12/11	AGREED		

Key to recommendations and symbols:

✓	Added to Formulary	Ⓢ	Specialist initiation only
✓R	Added to Formulary with restrictions	Ⓢ	Specialist use only
✗	Not added to Formulary	?	Awaiting final decision

Medicine name:	Paliperidone Palmitate (Xeplion®) *Janssen Pharmaceuticals Ltd*	Reason for consideration:	New medicine
Indication under review:	Maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.		
SMC/ HIS reference:	SMC 713/11 [Resubmission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Paliperidone prolonged release suspension for injection was non-inferior to another atypical antipsychotic depot injection in terms of control of schizophrenia symptoms over a 3-month period and was more effective than placebo in preventing relapse of schizophrenia.		
FND recommendation:	Add to Total Formulary Restricted to use under the overall supervision of a psychiatrist.	✓R	
ADTC Decision 12/12/11	AGREED		

Section 2: Medicines accepted by SMC – Minor or no changes to Formulary

Medicine name:	Dabigatran (Pradaxa®) *Boehringer Ingelheim Ltd*	Reason for consideration:	New indication
Indication under review:	Prevention of stroke and systemic embolism in adult patients with non-valvular AF with one or more risk factors. See SMC review for full details.		
SMC/ HIS reference:	SMC 672/11 [Full Submission] [Deferred Decision]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Dabigatran etexilate was at least as effective as standard oral anticoagulation at preventing stroke or systemic embolism in one large, open-label study in patients with atrial fibrillation and at least one risk factor for stroke. This was not associated with an increased risk of major bleeding. The economic case made supports the use of the proposed sequenced dosing regimen (whereby the dose is reduced from 150mg twice daily to 110mg twice daily in patients aged ≥ 80 years). This applies whether the alternative treatment is warfarin, aspirin or 'no treatment' (i.e. neither warfarin nor aspirin).		
FND recommendation:	Add to Total Formulary Restricted to use in accordance with National Consensus Statement available on the NHS HIS website (http://www.healthcareimprovementscotland.org/programmes/cardiovascular_disease/dabigatran_consensus_statement/dabigatran_consensus_statement.aspx)	✓R	
ADTC Decision 12/12/11	Restricted to patients currently receiving warfarin who have poor INR control despite evidence that they are complying, or patients with allergy or intolerable side effects from coumarin anticoagulants. Use in other patient groups remains non-Formulary. Further information regarding dabigatran can be found in the National Consensus Statement on the NHS HIS website.		

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✗ Not added to Formulary
S Specialist initiation only
S Specialist use only
? Awaiting final decision

Medicine name:	Rituximab (MabThera®) *Roche Products Limited*	Reason for consideration:	New indication
Indication under review:	Treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia (CLL) in combination with chemotherapy		
SMC/ HIS reference:	SMC 591/11 [Resubmission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Acknowledge new indication (Total Formulary) Restricted to use in accordance with regional protocol.		✓R
ADTC Decision 12/12/11	AGREED		

Medicine name:	Capecitabine (Xeloda®) *Roche Production Limited*	Reason for consideration:	New indication
Indication under review:	The adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer in combination with oxaliplatin.		
SMC/ HIS reference:	SMC 716/11 [Full Submission] [Deferred Decision][		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation and Formulary restriction:	Ⓢ Acknowledge new indication (Total Formulary) Restricted to use in accordance with regional protocol.		✓R
ADTC Decision 12/12/11	AGREED		

Key to recommendations and symbols:

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✗	Not added to Formulary	?	Awaiting final decision

Medicine name:	Golimumab (Simponi®) *MSD Ltd*	Reason for consideration:	New indication
Indication under review:	In combination with methotrexate, for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drug therapy including methotrexate has been inadequate. Golimumab, in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.		
SMC/ HIS reference:	SMC 733/11 [Full Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	The SMC restriction is for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005). Golimumab is restricted to use at a dose of 50 mg only. There are no head to head studies comparing golimumab with other TNFα inhibitors in the treatment of rheumatoid arthritis. Golimumab plus methotrexate was superior to methotrexate alone for the primary endpoint (ACR20 response and improvement in HAQ-DI) in patients with active rheumatoid arthritis despite methotrexate treatment. The economic case was demonstrated for golimumab when used at a dose of 50 mg. The economic case was not demonstrated for the 100 mg dose of golimumab. Golimumab is also licensed for use in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. SMC cannot recommend the use of golimumab in this setting, however, as the company submission related only to its use in patients with an inadequate response to methotrexate.		
FND recommendation and Formulary restriction:	Acknowledge new indication (Total Formulary) Restricted to use of the 50mg dose only in accordance with the British Society for Rheumatology (BSR) guidelines (2005). The 100mg dose remains non-Formulary.		✓R
ADTC Decision 12/12/11	AGREED		

Medicine name:	Somatropin (Saizen®) *Merck Serono Ltd*	Reason for consideration:	New formulation
Indication under review:	Growth failure or growth disturbance in children and adolescents and growth hormone replacement in adults with pronounced deficiency (see SMC advice for full indication details).		
SMC/ HIS reference:	SMC 737/11 [Abbreviated Submission]		
Summary of advice:	Accepted for use in NHS Scotland (Total Formulary)		
SMC/HIS restriction and comments:	This new formulation has been shown to be bioequivalent to the previously available freeze-dried formulation and is available at an equivalent cost. It is in a ready to use cartridge and does not require reconstitution.		
FND recommendation:	Acknowledge new formulation (Total Formulary). Noted also refereed to Paediatric Drugs and Therapeutics Committee		✓R
ADTC Decision 12/12/11	AGREED		

Key to recommendations and symbols:

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✗	Not added to Formulary	?	Awaiting final decision

Section 3: Medicines not recommended by SMC

Medicine name:	Aprepitant (Emend®) *Merck, Sharp & Dohme Ltd*	Reason for consideration:	New indication
Indication under review:	As part of combination therapy, for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.		
SMC/ HIS reference:	SMC 242/06 [Resubmission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Not added to the Formulary for this indication.		✘

Medicine name:	Dexamethasone (Ozurdex®) *Allergan Ltd*	Reason for consideration:	New preparation
Indication under review:	Treatment of adult patients with macular oedema following either branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).		
SMC/ HIS reference:	SMC 652/10 [Resubmission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	In two phase III studies dexamethasone 700 microgram intravitreal implant was superior to sham administration at day 90 for the proportion of patients with a best corrected visual acuity improvement of ≥15 letters. Longer-term effectiveness of treatment is uncertain. The submitting company did not provide a sufficiently robust clinical and economic analysis to gain acceptance by SMC.		
FND recommendation:	Not added to the Formulary for this preparation.		✘

Medicine name:	Naproxen/esomeprazole (Vimovo®) *AstraZeneca UK Ltd*	Reason for consideration:	New combination
Indication under review:	Symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS), in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)-associated gastric and/or duodenal ulcers and where treatment with lower doses of naproxen or of other NSAIDs is not considered sufficient.		
SMC/ HIS reference:	SMC 734/11 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	Studies have demonstrated that combined naproxen/esomeprazole was associated with a lower incidence of endoscopic gastric ulcers than NSAID alone and similar improvements in pain and functioning compared to a cyclo-oxygenase-2 selective inhibitor. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.		
FND recommendation:	Not added to the Formulary for this combination.		✘

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✘ Not added to Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only
? Awaiting final decision

Medicine name:	Cabazitaxel (Jevtana®) *Sanofi-Aventis*	Reason for consideration:	New medicine
Indication under review:	In combination with prednisone or prednisolone, cabazitaxel is licensed for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.		
SMC/ HIS reference:	SMC 735/11 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	In an open-label, multicentre, randomised, controlled phase III study in patients with metastatic hormone-refractory prostate cancer, treatment with cabazitaxel plus prednisone or prednisolone was associated with an extended median overall survival of 2.4 months compared with an alternative chemotherapy regimen. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.		
FND recommendation:	Not added to the Formulary.		✘

Medicine name:	Denosumab (Xgeva®) *Amgen*	Reason for consideration:	New indication
Indication under review:	Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours.		
SMC/ HIS reference:	SMC 752/11 [Non Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of denosumab 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.		
FND recommendation:	Not added to the Formulary for this indication.		✘

Section 4: Medicines accepted by SMC – Decisions deferred

Medicine name:	Ranibizumab (Lucentis®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults.		
SMC/ HIS reference:	SMC 732/11 [Full Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction is for use in patients with macular oedema secondary to central retinal vein occlusion (CRVO). Ranibizumab was associated with significant improvements in visual acuity during 6-month sham-controlled treatment in one study in patients with branch retinal vein occlusion and in one study in patients with central retinal vein occlusion. The benefits were considerable in patients with CRVO and there is a lack of alternative treatment options for these patients. The submitting company did not present a sufficiently robust economic analysis for ranibizumab in the treatment of BRVO to gain acceptance by SMC.		
FND recommendation:	Deferred to the relevant Clinical Director of Ophthalmology to allow for the development of clinical protocol. Interim non-Formulary status.		?
ADTC Decision 12/12/11	AGREED		

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✘ Not added to Formulary
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? Awaiting final decision

Medicine name:	Apixaban (Eliquis®) *Bristol-Myers Squibb Pharmaceuticals Ltd/Pfizer Ltd*	Reason for consideration:	New medicine
Indication under review:	Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.		
SMC/ HIS reference:	SMC 741/11 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In two large phase III double-blind comparative studies, in patients undergoing elective hip or knee replacement surgery, apixaban was superior to a low molecular weight heparin for the incidence of VTE and all cause death whilst incidence of major bleeding events was similar between groups.		
FND recommendation:	Deferred to allow consultation with orthopaedic surgeons and protocol development. Interim non-Formulary status.		?
ADTC Decision 12/12/11	AGREED		

Medicine name:	Telaprevir (Incivo®) *Janssen*	Reason for consideration:	New medicine
Indication under review:	In combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders.		
SMC/ HIS reference:	SMC 742/11 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In the pivotal phase III randomised study, the addition of telaprevir to current standard therapy in patients with genotype 1 chronic hepatitis C virus, who had failed previous therapy, significantly increased the proportion of patients who achieved a sustained virologic response.		
FND recommendation:	Deferred to allow consultation with the Hepatitis MCN for the development of a protocol for use. Interim non-Formulary status.		?
ADTC Decision 12/12/11	AGREED		

Medicine name:	Telaprevir (Incivo®) *Janssen*	Reason for consideration:	New medicine
Indication under review:	In combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve.		
SMC/ HIS reference:	SMC 743/11 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In the pivotal phase III randomised study, addition of telaprevir to current standard therapy in treatment-naïve patients with genotype 1 chronic hepatitis C virus, significantly increased the proportion of patients who achieved a sustained virologic response, even in patients treated for a shorter overall duration using response-guided therapy.		
FND recommendation:	Deferred to allow consultation with the Hepatitis MCN for the development of a protocol for use. Interim non-Formulary status.		?
ADTC Decision 12/12/11	AGREED		

Medicine name:	Boceprevir (Victrelis®) Treatment experienced patients *Merck, Sharpe and Dohme Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who have failed previous therapy.		
SMC/ HIS reference:	SMC 722/11 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In the pivotal phase III randomised study, addition of boceprevir to current standard therapy in patients with HCV, who had failed previous therapy, increased the proportion of patients who achieved a sustained virologic response.		
FND recommendation and Formulary restriction:	Deferred to allow consultation with the Hepatitis C MCN Interim non-Formulary status		?
ADTC Decision 12/12/11	AGREED		

Medicine name:	Boceprevir (Victrelis®) Treatment naive patients *Merck, Sharpe and Dohme Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who are previously untreated.		
SMC/ HIS reference:	SMC 723/11 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In the pivotal phase III randomised study, addition of boceprevir to current standard therapy in patients with HCV, who were previously untreated increased the proportion of patients with HCV who achieved a sustained virologic response.		
FND recommendation and Formulary restriction:	Deferred to allow consultation with the Hepatitis C MCN Interim non-Formulary status		?
ADTC Decision 12/12/11	AGREED		

Section 5: SMC advice that pertains to the GGC Paediatric Formulary

Medicine name:	Adalimumab (Humira®) *Abbott Laboratories*	Reason for consideration:	New indication
Indication under review:	In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 4 years.		
SMC/ HIS reference:	SMC 738/11 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations. The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adolescents aged 13 to 17 years and for rheumatoid arthritis in adults.		
FND recommendation:	Deferred for consideration by the Paediatric Drugs and Therapeutics Committee. Interim Non Formulary Status		?
ADTC Decision 12/12/11	AGREED		

Key to recommendations and symbols:

✓	Added to Formulary	S	Specialist initiation only
✓R	Added to Formulary with restrictions	S	Specialist use only
✗	Not added to Formulary	?	Awaiting final decision

Medicine name:	Abatacept (Orencia®) *Bristol-Myers Squibb Pharmaceuticals Ltd*	Reason for consideration:	New indication
Indication under review:	In combination with methotrexate, abatacept is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other disease modifying antirheumatic drugs (DMARDs) including at least one tumour necrosis factor (TNF) inhibitor. It has not been studied in children under 6 years old.		
SMC/ HIS reference:	SMC 618/10 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Abatacept is an anti-rheumatic agent that prevents T-lymphocyte activation. Abatacept in combination with methotrexate has been accepted for restricted use in adults with severe active rheumatoid arthritis in line with the recommendations of the NICE Multiple Technology Appraisal no 195. NHS Quality Improvement Scotland advised that these recommendations were valid for NHS Scotland.		
Financial Impact:			
Governance issues:			
FND recommendation:	Deferred for consideration by the Paediatric Drugs and Therapeutics Committee. Interim Non Formulary Status		?
ADTC Decision 12/12/11			

Section 6: Other Formulary decisions – Appeals, reviews and NICE/SIGN guidance

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✗ Not added to Formulary
S Specialist initiation only
S Specialist use only
? Awaiting final decision