NEW DRUG RECOMMENDATIONS
FEBRUARY 2012

NHS Greater Glasgow and Clyde

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

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] [Deferred Decision]**		
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:	**Add to Total Formulary** **Restricted to use by specialists and in accordance with local protocol.**		✓R
ADTC Decision 13/02/12	**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] [Deferred Decision]**		
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:	**Add to Total Formulary** **Restricted to use by specialists and in accordance with local protocol.**		✓R
ADTC Decision 13/02/11	**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] [Deferred Decision]**		
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:	**Add to Total Formulary** **Restricted to use by specialists and in accordance with local protocol.**		✓R
ADTC Decision 13/02/12	**AGREED**		

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:	**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] [Deferred Decision]**		
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:	**Add to Total Formulary** **Restricted to use by specialists and in accordance with local protocol.**		✓R
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Linagliptin (Trajenta®)** *Boehringer Ingelheim / Eli Lilly and Company Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of type 2 diabetes mellitus to improve glycaemic control in adults (as monotherapy and as combination therapy).**		
SMC/ HIS reference:	**SMC 746/11 [Full Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: In combination therapy with metformin when diet and exercise plus metformin alone does not provide adequate glycaemic control in patients for whom the addition of a sulphonylurea is inappropriate. In two randomised double-blind, controlled studies, linagliptin in combination with metformin was found to be non-inferior to a sulphonylurea plus metformin, and superior to placebo plus metformin in controlling glycaemia, measured by the change in glycosylated haemoglobin (HbA1c). Linagliptin was associated with similar rates of hypoglycaemia and changes in weight when compared with placebo. Linagliptin is one of a number of medicines in this class, some of which are available at a lower acquisition cost. SMC cannot recommend the use of linagliptin as monotherapy or in combination with metformin and a sulphonylurea as the company's submission related only to its use in combination with metformin.		
FND recommendation:	**Add to Total Formulary** **Restricted to use in combination therapy with metformin when diet and exercise plus metformin alone does not provide adequate glycaemic control in patients for whom the addition of a sulphonylurea is inappropriate. In primary care, it is expected that initiation would follow interaction between the GP/Diabetic Nurse Specialist and the consultant contact within the acute sector.**		✓R
ADTC Decision 13/02/12	**AGREED subject to the addition of "specialist initiation"**		

Medicine name:	**Rilpivirine (Edurant®)** *Tibotec (division of Janssen-Cilag)*	Reason for consideration:	**New medicine**
Indication under review:	**Rilpivirine in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL.**		
SMC/ HIS reference:	**SMC 758/12 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	The non-inferiority of rilpivirine over another non-nucleoside reverse transcriptase inhibitor (when given in combination with two nucleoside reverse transcriptase inhibitors) for virological response was demonstrated in two phase III, comparative, multi-centre studies in antiretroviral treatment-naïve patients.		
FND recommendation:	**Add to Total Formulary** **Restricted to use by HIV specialists**		✓R
ADTC Decision 13/02/12	**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

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

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] [Deferred Decision]**		
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:	**Not added to the Formulary** **Clinicians do not wish to use this medicine. Suitable alternatives on Formulary**		✘
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Dabigatran etexilate (Pradaxa®)** *Boehringer Ingelheim Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.**		
SMC/ HIS reference:	**SMC 466/08 [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:	**Not added to the Formulary for this indication** **Clinicians do not wish to use this medicine. Suitable alternatives on Formulary**		✘
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Emtricitabine/ tenofovir/ rilpivirine (Eviplera®)** *Gilead Sciences Limited*	Reason for consideration:	**New combination**
Indication under review:	**Treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.l**		
SMC/ HIS reference:	**SMC 759/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	As with other antiretroviral therapies, genotypic resistance testing should inform the use of Eviplera®. This combination tablet has been shown to be bioequivalent to the individual components given separately. It is available at pro rata cost to the individual components and may be used to simplify the regimen of patients for whom this combination of HIV therapies is appropriate at the doses provided in this fixed dose combination.		
FND recommendation:	Ⓢ **Add to Total Formulary** **Restricted to use by HIV specialists**		✓R
ADTC Decision 13/02/12	**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:	**Exenatide Once Weekly (Bydureon®)** *Eli Lilly and Company Limited*	Reason for consideration:	**New formulation**
Indication under review:	**Treatment of type 2 diabetes mellitus in combination with metformin, sulphonylurea, thiazolidinedione, metformin and sulphonylurea, metformin and thiazolidinedione in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.**		
SMC/ HIS reference:	**SMC 748/11 [Full Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC Restriction: Exenatide once weekly is restricted to use as a third line treatment option. The economic case for exenatide once weekly for second line use in combination with metformin in place of a sulphonylurea has not been made. In four randomised comparative studies in patients with type II diabetes and receiving oral anti-diabetic agents and/or diet and exercise regimens, exenatide once weekly was superior to the comparators for change in HbA1c. However in a fifth study exenatide once weekly was not superior to another glucagon-like peptide-1 receptor agonist.		
FND recommendation:	**Acknowledge new formulation (Total Formulary)** **Restricted to specialist initiation for use as a third line treatment option in combination with other agents.**		✓R
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Fentanyl single dose nasal spray (Instanyl®)** *Abbott Laboratories*	Reason for consideration:	**New presentation**
Indication under review:	**For the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.**		
SMC/ HIS reference:	**SMC 750/11 [Abbreviated Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. SMC restriction: to patients who are unsuitable for other short-acting oral opioids (e.g. oral morphine) as an alternative to other buccal and sublingual fentanyl preparations. It should be noted that the doses of fentanyl nasal spray are significantly lower than doses of fentanyl given by other routes of administration for this indication. In a pharmacokinetic study in healthy volunteers, this single dose fentanyl nasal spray presentation was shown to be bioequivalent to the multi-dose nasal spray presentation and is available at equivalent cost per dose.		
FND recommendation:	**Not added to the Formulary for this presentation following consultation with the Palliative Care MCN. Suitable alternatives on Formulary**		✗
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Nevirapine prolonged tablets (Viramune®)** *Boehringer Ingelheim Ltd*	Reason for consideration:	**New formulation**
Indication under review:	**In combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children three years and above and able to swallow tablets.**		
SMC/ HIS reference:	**SMC 760/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Once daily dosing with the nevirapine prolonged release formulation demonstrated non-inferior efficacy to the immediate release nevirapine formulation at 48 weeks in both treatment-naïve and treatment-experienced patients. When combined with other HIV therapies the once daily formulation may provide a more convenient dosing schedule for patients.		
FND recommendation:	**Acknowledge new formulation (Total Formulary)** **Restricted to use by HIV specialists**		✓R
ADTC Decision 13/02/12	**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:	**Rivaroxaban (Xarelto®)** *Bayer PLC*	Reason for consideration:	**New indication**
Indication under review:	**The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.**		
SMC/ HIS reference:	**SMC 756/12 [Full Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: Rivaroxaban is accepted for use in patients who have poor INR control despite evidence that they are complying with a coumarin anticoagulant and in patients who are allergic to or unable to tolerate coumarin anticoagulants. Rivaroxaban was non-inferior to standard oral anticoagulation at preventing stroke or systemic embolism in one large, double-blind study in patients with atrial fibrillation and moderate to high risk of stroke. This was not associated with a significantly increased risk of major or non-major clinically relevant bleeding. The submitting company made an economic case for rivaroxaban use in the restricted patient population described above.		
FND recommendation:	**Acknowledge new indication (Total Formulary).** **Restricted to use in patients who have poor INR control despite evidence that they are complying with a coumarin anticoagulant and in patients who are allergic or unable to tolerate coumarin anticoagulants, 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 13/02/12	**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 use in this indication can be found in the National Consensus Statement on the NHS HIS website.**		

Section 3: Medicines not recommended by SMC

Medicine name:	**Ranolazine (Ranexa®)** *A Menarini Pharma UK SRL*	Reason for consideration:	**New medicine**
Indication under review:	**As add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta-blockers and/or calcium antagonists).**		
SMC/ HIS reference:	**SMC 565/09 [2nd Resubmission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	When added to standard doses of antianginal drugs, ranolazine increased exercise duration at trough drug levels compared with placebo after 12 weeks treatment. Although significant the effect size was modest. The submitting company did not present a sufficiently robust clinical and economic case to gain acceptance by SMC.		
FND recommendation:	**Not added to the Formulary.**	✘	

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:	**Entecavir (Baraclude®)** *Bristol-Myers Squibb Pharmaceuticals Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of chronic hepatitis B virus (HBV) infection in adults with decompensated liver disease.**		
SMC/ HIS reference:	**SMC 747/11 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Entecavir demonstrated a superior virological response in adults with chronic HBV and decompensated liver disease compared with another nucleoside/nucleotide analogue. However there is no comparative evidence versus the relevant comparator. 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 indication.**		✘

Medicine name:	**Dexamethasone ocular implant (Ozurdex®)** *Allergan*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.**		
SMC/ HIS reference:	**SMC 751/11 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	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.**		✘

Medicine name:	**Aztreonam for nebulisation (Cayston®)** *Allergan*	Reason for consideration:	**New formulation**
Indication under review:	**The suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged 18 years and older.**		
SMC/ HIS reference:	**SMC 753/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Aztreonam lysine has demonstrated superiority in improving lung function and respiratory symptoms in one 28-day active-controlled study and two 28-day placebo-controlled studies in patients with cystic fibrosis and chronic Pseudomonas aeruginosa infection. There are limited data to support the sustainability of the observed short term benefit over subsequent courses of treatment. 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 company did not present a sufficiently robust economic case to gain acceptance by SMC.		
FND recommendation:	**Not added to the Formulary for this formulation.**		✘

Medicine name:	**Eculizumab (Soliris®)** *Alexion Pharma UK Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of patients with atypical haemolytic uremic syndrome (aHUS).**		
SMC/ HIS reference:	**SMC 767/12 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	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.**		✘

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:	**Lapatinib (Tyverb®)** *GlaxoSmithKline*	Reason for consideration:	**New medicine**
Indication under review:	**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.**		
SMC/ HIS reference:	**SMC 768/12 [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 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.		
FND recommendation:	**Not added to the Formulary.**		✘

Medicine name:	**Panitumumab (Vectibix®)** *Amgen*	Reason for consideration:	**New medicine**
Indication under review:	**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).**		
SMC/ HIS reference:	**SMC 769/12 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	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.**		✘

Medicine name:	**Pemetrexed (Alimta®)** *Eli Lilly and Company Limited*	Reason for consideration:	**New indication**
Indication under review:	**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.**		
SMC/ HIS reference:	**SMC 770/12 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC has previously issued not recommended advice for pemetrexed monotherapy for the maintenance treatment of non-small cell lung cancer in patients who have had first line treatment with cisplatin plus gemcitabine, paclitaxel or docetaxel. The marketing authorisation for pemetrexed has recently been extended to allow its use as maintenance therapy in patients who have had first-line treatment with cisplatin plus pemetrexed. The holder of the marketing authorisation has not made a submission to SMC regarding the use of this product in this setting. As a result we cannot recommend its use within NHSScotland.		
FND recommendation:	**Not added to the Formulary for this indication.**		✘

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:	**Prednisone modified-release tablets (Lodotra®)** *Napp Pharmaceuticals*	Reason for consideration:	**New formulation**
Indication under review:	**Treatment of moderate to severe, active rheumatoid arthritis in adults particularly when accompanied by morning stiffness.**		
SMC/ HIS reference:	**SMC 771/12 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	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 formulation.**		✘

Medicine name:	**Saxagliptin (Onglyza®)** *AstraZeneca*	Reason for consideration:	**New indication**
Indication under review:	**Adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.**		
SMC/ HIS reference:	**SMC 772/12 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	The holder of the marketing authorisation has not made a submission to SMC regarding this product in combination with insulin in type 2 diabetes mellitus. As a result we cannot recommend its use within NHSScotland.		
FND recommendation:	**Not added to the Formulary for this indication.**		✘

Medicine name:	**Tapentadol (Palexia®) film coated tablets** *Grunenthal Ltd*	Reason for consideration:	**New formulation**
Indication under review:	**Relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.**		
SMC/ HIS reference:	**SMC 773/12 [Non Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	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 formulation.**		✘

Section 4: Medicines accepted by SMC – Decisions deferred

Medicine name:	**Erlotinib (Tarceva®)** *Roche Products Ltd*	Reason for consideration:	**New indication**
Indication under review:	**First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations.**		
SMC/ HIS reference:	**SMC 749/11 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	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.		
FND recommendation:	**Deferred to allow consultation with the Regional Cancer Advisory Group.** **Interim non-Formulary status**		?

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:	**Rivaroxaban (Xarelto®)** *Bayer PLC*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.**		
SMC/ HIS reference:	**SMC 755/12 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Rivaroxaban has been shown to be non-inferior to standard anticoagulant therapy including a low molecular weight heparin in combination with a vitamin K antagonist for the treatment of proximal DVT and prevention of recurrence. Experience with rivaroxaban in this indication for more than 12 months is limited therefore the cost-effectiveness of indefinite treatment has not been demonstrated.		
FND recommendation:	**Deferred to allow consultation with the Thrombosis Group.** **Interim non-Formulary status**		**?**
ADTC Decision 13/02/12			

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

Medicine name:	**Tocilizumab (RoActemra®)** *Roche Products Limited*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate.**		
SMC/ HIS reference:	**SMC 754/12 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Tocilizumab was superior to placebo in reducing disease activity and fever in patients with persistent active systemic juvenile idiopathic arthritis despite treatment with NSAIDs and corticosteroids. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.		
FND recommendation:	**Decision deferred for consideration by the Paediatric Drugs and Therapeutics Committee** **Interim Non Formulary Status**		**?**
ADTC Decision 13/02/12			

Medicine name:	**Midazolam (Buccolam®)** *ViroPharma Ltd*	Reason for consideration:	**New formulation**
Indication under review:	**Treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years).**		
SMC/ HIS reference:	**SMC 757/12 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Midazolam given via the buccal route was considered at least non-inferior to rectally administered benzodiazepine in terminating acute prolonged seizures. The economic case was demonstrated for midazolam compared to rectal diazepam.		
FND recommendation:	**Decision deferred for consideration by the Paediatric Drugs and Therapeutics Committee** **Interim Non Formulary Status**		**?**
ADTC Decision 13/02/12			

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

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

Medicine name:	**Budesonide (Rhinocort Aqua®)** *Astra Zeneca*	Indication:	**Allergic Rhinitis**
Reason for consideration:	**Formulary Appeal**	SMC decision:	**N/A**
FND recommendation, restrictions on use and comments: **Move to Preferred List, replacing mometasone nasal spray which will be moved to Total Formulary. (Adult Formulary)**			✓R
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Carmellose sodium (Celluvisc®)** *Allergan*	Indication:	**Dry Eye.**
Reason for consideration:	**Formulary Appeal**	SMC decision:	**October 2010 : Formulary Section Review.** **Carmellose sodium (Celluvisc®) added to Total Formulary for tear deficiency and dry-eye conditions. Restricted to use only in those patients with severe dry eyes in addition to external eye or corneal conditions who demonstrate intolerance to preservatives.**
FND recommendation, restrictions on use and comments: **Appeal not upheld on the basis of insufficient evidence and potential cost implications.**			✓R
ADTC Decision 13/02/12	**AGREED**		

Medicine name:	**Dasatinib, Nilotinib, Imatinib**	Reason for consideration:	**NICE MTA**
Indication under review:	**Multiple Myeloma (First Line)**		
SMC/ HIS reference:	**NICE MTA 241 (partial update of previous guidance to review Imatinib resistance/intolerance)**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	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. 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. High-dose imatinib1 is not recommended for the treatment of chronic, accelerated or blast-crisis phase Philadelphia-chromosome-positive CML that is resistant to standard-dose imatinib. People who are currently receiving dasatinib or high-dose imatinib for the treatment of CML should have the option to continue treatment until they and their clinicians consider it appropriate to stop.		
FND recommendation and Formulary restriction:	**Deferred for consultation with the Regional Cancer Advisory Group.**		?
ADTC Decision 13/02/12	**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