NEW DRUG RECOMMENDATIONS NOVEMBER-DECEMBER 2012

NHS Greater Glasgow and Clyde

Section 1: Medicines accepted by SMC – Included in Formulary (Major changes)

Medicine name:	Aclidinium bromide (Eklira Genuair®) *Almirall S.A.*	Reason for consideration:	New medicine
Indication under review:	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)		
SMC/ HIS reference:	SMC 810/12 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In two phase III studies, aclidinium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [FEV_1]) after 12 weeks and 24 weeks.		
FND recommendation:	Included in the GCC Total Formulary for the indication in question.		✓
ADTC Decision 10/12/12	AGREED		

Medicine name:	5-aminolaevulinic acid (as hydrochloride) (Ameluz®) *Biofrontera Bioscience GmbH*	Reason for consideration:	New medicine
Indication under review:	Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).		
SMC/ HIS reference:	SMC 811/12 [Full Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	In a multi-centre, randomised, observer-blind, controlled phase III study, 5-aminolaevulinic acid gel met pre-specified non-inferiority criteria compared with an alternative topical agent in terms of complete clearance of actinic keratosis lesions, 12 weeks after the last of up to two sessions of photodynamic therapy. The treatment difference was sufficient to demonstrate superiority over the alternative topical agent.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question restricted to use by consultant dermatologists.		✓R
ADTC Decision 10/12/12	AGREED		

Medicine name:	Dexmedetomidine (Dexdor®) *Orion Pharma UK*	Reason for consideration:	New medicine
Indication under review:	For sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3).		
SMC/ HIS reference:	SMC 784/12 [Full Submission] [Deferred Decision]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Dexmedetomidine was as effective as propofol and midazolam in maintaining the target depth of sedation in ICU patients. The median duration of mechanical ventilation was numerically shorter with dexmedetomidine than with propofol and significantly shorter than with midazolam.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question restricted to use in accordance with local protocol.		✓R
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Medicine name:	Ferric Carboxymaltose (Ferinject®) *Vifor Pharma UK Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests.		
SMC/ HIS reference:	SMC 463/08 [2nd Resubmission] [Deferred Decision]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	Use is restricted to administration by intravenous infusion within the licensed indication but excluding use in patients receiving haemodialysis Ferric carboxymaltose was superior to oral ferrous sulphate in raising haemoglobin levels in non-dialysis-dependent patients with chronic kidney disease and iron deficiency anaemia.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Use as an IV infusion is restricted to when oral iron preparations are ineffective or cannot be used and standard IV iron is inappropriate due to its administration schedule. This preparation is considerably more expensive than many other IV iron preparations. Use in patients on haemodialysis or use as a bolus injection was not recommended by SMC and remains non-Formulary.		✓R
ADTC Decision 10/12/12	AGREED		

Medicine name:	Iron isomaltoside 1000, 100mg/mL solution (Monofer®) *Pharmacosmos UK*	Reason for consideration:	New medicine
Indication under review:	Treatment of iron deficiency anaemia in the following conditions: • When oral iron preparations are ineffective or cannot be used; • Where there is a clinical need to deliver iron rapidly.		
SMC/ HIS reference:	SMC 697/11 [Full Submission] [Deferred Decision]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction is to administration by high dose infusion within the licensed indication but excluding use in patients receiving haemodialysis. The manufacturer's economic case did not consider the cost-effectiveness of iv bolus administration or use in haemodialysis patients Efficacy data are limited to two small open-label non comparative studies in patients with chronic kidney disease and chronic heart failure. Haemoglobin levels significantly increased from baseline in one study only.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Use as an IV infusion is restricted to when oral iron preparations are ineffective or cannot be used and standard IV iron is inappropriate due to its administration schedule. This preparation is considerably more expensive than many other IV iron preparations. Use in patients on haemodialysis or use as a bolus injection was not recommended by SMC and remains non-Formulary.		✓R
ADTC Decision 10/12/12	AGREED		

Medicine name:	Nepafenac (Nevanac®) eye drops *Alcon Laboratories (UK) Ltd*	Reason for consideration:	New medicine
Indication under review:	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.		
SMC/ HIS reference:	SMC 813/12 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In the pivotal study which included diabetic patients who had undergone cataract surgery, nepafenac eye drops significantly reduced the incidence of macular oedema compared to vehicle.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question restricted to diabetic patients with retinopathy		✓R
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Medicine name:	Perampanel film coated tablets (Fycompa®) *Eisai Ltd*	Reason for consideration:	New medicine
Indication under review:	Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.		
SMC/ HIS reference:	SMC 819/12 [Full Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	In three placebo-controlled studies in patients with uncontrolled partial-onset seizures, perampanel was superior to placebo in terms of the proportion of patients experiencing a ≥50% reduction in partial seizure frequency per 28 days. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of perampanel. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary and Paediatric Formulary for the indication in question restricted to initiation by specialists in epilepsy.		✓R
ADTC Decision 10/12/12	AGREED		

Medicine name:	Ustekinumab injection (Stelara®) *Jannsen-Cilag Ltd.*	Reason for consideration:	New medicine
Indication under review:	Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen and UVA treatment (PUVA).		
SMC/ HIS reference:	SMC 572/09 [Full Submission] [Deferred Decision]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	Significantly more patients treated with ustekinumab achieved at least 75% improvement in their Psoriasis Area and Severity Index (PASI) score at week 12, compared with those treated with a tumour necrosis factor alpha antagonist. Continued treatment should be restricted to patients who achieve a PASI 75% response within 16 weeks. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ustekinumab. This SMC advice is dependent upon the continuing availability of the patient access scheme in NHS Scotland		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question restricted to specialist use. Continued treatment should be restricted to patients who achieve a PASI 75% response within 16 weeks. Formulary status (and SMC advice) is contingent upon the continuing availability of the patient access scheme.		✓R
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
- ✓ Included on Formulary
- ✓R Included on Formulary with restrictions
- ✗ Not included on Formulary
- Ⓢ Specialist initiation only
- Ⓢ Specialist use only

Section 2: Medicines accepted by SMC – Included in Formulary (Minor changes)

Medicine name:	Bortezomib (Velcade®) subcutaneous injection *Janssen-Cilag Ltd*	Reason for consideration:	New formulation
Indication under review:	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.		
SMC/ HIS reference:	SMC 822/12 [Abbreviated Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included on GGC Total Formulary for the indication in question restricted to use in accordance with regional protocols.		✓R
ADTC Decision 10/12/12	AGREED		

Medicine name:	Lanthanum carbonate (Fosrenol®) *Shire Pharmaceuticals Contracts Ltd*	Reason for consideration:	New formulation
Indication under review:	As a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Lanthanum is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.		
SMC/ HIS reference:	SMC 821/12 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: As a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required. Lanthanum carbonate is as effective as calcium carbonate in reducing phosphate to target levels.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question restricted to use as a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required.		✓R
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

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] [Deferred Decision]		
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:	Ⓢ Included in the GGC Total Formulary restricted to use in accordance with GGC Protocol. Use in patients with branch RVO was not recommended by SMC and remains non-Formulary		✓R
ADTC Decision 10/12/12	AGREED		

Section 3: Medicines accepted by SMC – Not included in Formulary

Medicine name:	Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT®) *Daiichi Sankyo UK Ltd*	Reason for consideration:	New combination
Indication under review:	In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.		
SMC/ HIS reference:	SMC 823/12 [Abbreviated Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Two double-blind randomised studies of triple versus dual therapy demonstrated significantly better outcomes for patients in the triple therapy group in terms of the proportion of patients reaching target blood pressure and reduction in mean systolic and diastolic blood pressure. In patients for whom concomitant use of these medicines is appropriate it allows administration of a single tablet at a lower cost compared to a dual combination product plus single component. Angiotensin receptor blockers are an alternative to angiotensin-converting-enzyme (ACE) inhibitors where these are not tolerated. These fixed dose combinations are among many options for the treatment of hypertension, many of which are less expensive.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question because the medicine does not represent sufficient added benefit to other comparator medicines (see below) to treat the condition in question which are already available in the formulary. – Comparators in section 2.2 of the GGC Formulary – Comparators in section 2.5 of the GGC Formulary – Comparators in section 2.6 of the GGC Formulary		✗
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Section 4: Medicines accepted by SMC – Not included pending protocol/consultation

Medicine name:	Ranibizumab (Lucentis®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of visual impairment due to diabetic macular oedema (DMO) in adults.		
SMC/ HIS reference:	SMC 711/11 [Resubmission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: Treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline. Ranibizumab significantly improved visual acuity over 12 months compared with standard laser photocoagulation treatment. Open label extension results up to 3 years suggest maintenance of effect. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.		
FND recommendation:	Not included in the GGC Adult Formulary pending protocol (relevant Clinical Director of Ophthalmology)		✘
ADTC Decision 10/12/12	AGREED		

Section 5: Medicines not recommended by SMC

Medicine name:	Argatroban (Exembol®) *Mitsubishi Pharma Europe Ltd*	Reason for consideration:	New medicine
Indication under review:	Anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.		
SMC/ HIS reference:	SMC 812/12 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	Argatroban produces anticoagulant effects in adults with heparin-induced thrombocytopenia type II and there is limited evidence that it may be associated with a reduction in thrombosis, and deaths due to thrombosis. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Medicine name:	Adalimumab (Humira®) *Abbott Laboratories*	Reason for consideration:	New indication
Indication under review:	Treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.		
SMC/ HIS reference:	SMC 824/12 [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. Adalimumab remains a treatment option for adults with severe active Crohn's disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy, in line with the NICE (Multiple) Technology Appraisal Guidance No 187. Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.		
FND recommendation:	Not added to the GGC Adult Formulary for the indication in question.		✘

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
S Specialist initiation only
S Specialist use only

Medicine name:	Interferon beta-1a (Rebif®) *Merck Serono*	Reason for consideration:	New indication
Indication under review:	Patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.		
SMC/ HIS reference:	SMC 825/12 [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 GGC Adult Formulary for the indication in question.		✘

Medicine name:	Pazopanib (Votrient®) *GlaxoSmithKline UK*	Reason for consideration:	New indication
Indication under review:	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.		
SMC/ HIS reference:	SMC 820/12 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

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 [Full Submission] [Independent Review Panel Assessment]		
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, but not uncommon in studies of patients with stable angina pectoris. The submitting company did not present a sufficiently robust clinical and economic case to gain acceptance by the Independent Review Panel (IRP).		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
S Specialist initiation only
S Specialist use only

Medicine name:	Racecadotril (Hidrasec Infants®) *Abbott Healthcare Products Ltd*	Reason for consideration:	New medicine
Indication under review:	Complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition.		
SMC/ HIS reference:	SMC 818/12 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	Racecadotril was significantly better than placebo in reducing mean stool output at 48 hours in children with acute diarrhoea treated in hospital. There is insufficient evidence that it improves recovery rate. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.		
FND recommendation:	Not included in the GGC Paediatric Formulary for the indication in question.		✘

Medicine name:	Racecadotril (Hidrasec®) *Abbott Healthcare Products Ltd*	Reason for consideration:	New medicine
Indication under review:	Symptomatic treatment of acute diarrhoea in adults when casual treatment is not possible.		
SMC/ HIS reference:	SMC 832/12 [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 included in the GGC Adult Formulary for the indication in question.		✘

Section 6: Medicines accepted by SMC –consideration in GGC Paediatric Formulary only

Medicine name:	Sildenafil (as citrate) (Revatio®) tablets and oral powder for oral solution *Pfizer UK*	Reason for consideration:	New indication/formulation
Indication under review:	Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.		
SMC/ HIS reference:	SMC 809/12 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service. SMC has previously accepted this orphan indication for oral sildenafil for restricted use within NHS Scotland for the treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. Sildenafil is listed in the British National Formulary for Children 2011-2012 for use in pulmonary hypertension after cardiac surgery, weaning from nitric oxide, idiopathic pulmonary arterial hypertension, persistent pulmonary hypertension of the newborn.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question restricted to specialist use only.		✓R
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Section 7: Other Formulary decisions – Appeals, reviews, NICE/SIGN guidance

Medicine name:	Denosumab (Xgeva®) *Amgen*	Indication:	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.
Reason for consideration:	NICE MTA265	SMC decision:	Supersedes SMC 752/11 [Non Submission]
FND recommendation, restrictions on use and comments: Not included in the GGC Formulary pending protocol (Regional Cancer Advisory Group) 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. Denosumab is not recommended for preventing skeletal-related events in adults with bone metastases from prostate cancer. Adults with bone metastases from solid tumours currently receiving denosumab for the prevention of skeletal-related events that is not recommended according to 1.1 and 1.2 should be able to continue treatment until they and their clinician consider it appropriate to stop			✘
ADTC Decision 10/12/12	AGREED		

Medicine name:	Calcium 300mg and colecalciferol 200 unit tablets (Adcal D3® Caplets) *ProStraken*	Indication:	As an adjunct to specific therapy for osteoporosis and in situations requiring therapeutic supplementation of malnutrition e.g. in pregnancy and established vitamin D dependent osteomalacia and the prevention and treatment of calcium deficiency/vitamin D deficiency especially in the housebound and institutionalised elderly subjects.
Reason for consideration:	Formulary Section Review	SMC decision:	N/A
FND recommendation, restrictions on use and comments: Included in the Total Formulary for the indication in question restricted to those patients who cannot tolerate the chewable tablet formulation of Calcium and VitaminD3®.			✓R
ADTC Decision 10/12/12	AGREED		

Medicine name:	Calcium 500mg and cholecalciferol 800 unit chewable tablets (Kalcipos-D®) *Meda Pharmaceuticals*	Indication:	– Prevention and treatment of calcium and vitamin D deficiency in the elderly – Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency
Reason for consideration:	Formulary Section Review New preparation	SMC decision:	SMC 718/11 [Abbreviated] Accepted for use in NHS Scotland [Deferred Decision]
FND recommendation, restrictions on use and comments: Not included in the GGC Adult Formulary for the indication in question because the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary.			✘
ADTC Decision 10/12/12	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
S Specialist initiation only
S Specialist use only

Medicine name:	Zopiclone 3.75mg, 7.5mg tablets *Meda Pharmaceuticals*	Indication:	Insomnia (short-term use)
Reason for consideration:	Informal review	SMC decision:	N/A
FND recommendation, restrictions on use and comments: Zopiclone is to replace temazepam on the Preferred List of the GGC Adult Formulary. Resulting from supply problems which are not expected to be resolved in the near to medium-term, temazepam is now considerably more expensive than zopiclone			✓
ADTC Decision 10/12/12	AGREED		

Medicine name:	Trospium modified-release (Regurin XL®) capsules *Speciality European*	Indication:	Symptomatic relief of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with an overactive bladder.
Reason for consideration:	Formulary Appeal	SMC decision:	Not applicable
FND recommendation, restrictions on use and comments: Included in the Preferred List for the indication in question. In addition, solifenacin should be moved to the Total Formulary			✓
ADTC Decision 10/12/12	Included in the Preferred List for the indication in question. Solifenacin should remain on the Preferred List.		

Key to recommendations and symbols:

✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
S Specialist initiation only
S Specialist use only