Greater Glasgow and Clyde Area Drug and Therapeutics Committee
Formulary and New Drugs Sub-Committee

NEW DRUG RECOMMENDATIONS
JUNE/JULY 2013

NHS Greater Glasgow and Clyde

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

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 [Resubmission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Argatroban produces anticoagulant effects in adults with heparin-induced thrombocytopenia type II. However there is limited evidence that the anticoagulant effects are associated with a reduction in thrombosis and deaths due to thrombosis.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use where other options are not suitable or available (in accordance with local protocol which will be updated).		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Pirfenidone (Esbriet®) *InterMune*	Reason for consideration:	New medicine
Indication under review:	In adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).		
SMC/ HIS reference:	SMC 835/13 [Resubmission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: For use in patient with a predicted forced vital capacity (FVC) less than or equal to 80%. Pirfenidone reduced the decline in lung function parameters associated with IPF compared to placebo in a pooled analysis of two similarly designed phase lll studies. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pirfenidone. 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.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use only in patients with a predicted forced vital capacity (FVC) less than or equal to 80% in accordance with local protocol where the Interstitial Lung Disease Multidisciplinary Team have agreed it is appropriate.		✓R
ADTC Decision 12/08/13	Ⓢ Included in the GGC Total Formulary pending protocol. Restricted to specialist use only in patients with a predicted forced vital capacity (FVC) less than or equal to 80% where an Interstitial Lung Disease Multidisciplinary Team have agreed it is appropriate.		

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 diabetic macular oedema (DMO) in adults.		
SMC/ HIS reference:	SMC 711/11 [Resubmission] [Deferred Decision]		
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:	Ⓢ Included in the GGC Total Formulary for the indication in question pending protocol.		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Sugammadex injection (Bridion®) *Merck Sharp & Dohme Ltd*	Reason for consideration:	New indication
Indication under review:	Routine reversal of neuromuscular blockade induced by rocuronium or vecuronium in adult and paediatric patients.		
SMC/ HIS reference:	SMC 527/09 [Resubmission] [Deferred Decision]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/chest surgery) or where prompt reversal of neuromuscular block is required. Sugammadex, when administered after rocuronium or vecuronium, has been shown to provide more rapid reversal of moderate and profound neuromuscular blockade than an anti-cholinesterase comparator. Sugammadex is significantly more expensive than conventional treatments used to reverse neuromuscular blockade		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use for the routine reversal of neuromuscular blockade induced by rocuronium or vercuronium in high risk adults (only rocuronium in children/adolescents). Prescribing note: High risk patients are defined as: - morbid obesity - significant respiratory disease or reduced respiratory reserve - significant coronary disease - major abdominal/chest surgery		✓R
ADTC Decision 12/08/13	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:	Abatacept (Orencia®) for subcutaneous injection *Bristol-Myers Squibb Pharmaceuticals Ltd*	Reason for consideration:	New formulation
Indication under review:	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs including methotrexate or a TNF-alpha inhibitor.		
SMC/ HIS reference:	SMC 888/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	SMC has previously accepted abatacept 250mg powder for concentrate for solution for infusion (Orencia®) for restricted use in NHS Scotland for this indication. Abatacept 125mg/mL subcutaneous injection (Orencia®) is more expensive on a mg-for-mg basis than abatacept 250mg powder for concentrate for solution for infusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abatacept. 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.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use only.		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Alteplase (Actilyse Cathflo®) *Boehringer Ingelheim*	Reason for consideration:	New presentation
Indication under review:	Thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.		
SMC/ HIS reference:	SMC 717/11 [Abbreviated Submission] [Deferred Decision]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	The SMC restriction was for use where alteplase is the product of choice for the treatment of occluded venous access devices. This is a new formulation introduced for this extension to the alteplase marketing authorisation and the 2ml vial is the only presentation licensed for this indication.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use and second line use after urokinase		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Calcium polystyrene sulphonate (Sorbisterit®) *Stanningley Pharma Ltd*	Reason for consideration:	New presentation
Indication under review:	Treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment.		
SMC/ HIS reference:	SMC 890/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Sorbisterit® provides an alternative to the existing proprietary product at a lower cost. The dose of Sorbisterit® and the existing proprietary product differ as the strength of the active ingredient varies slightly.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use only.		✓R
ADTC Decision 12/08/13	AGREED subject to restriction being changed to "hospital use" only.		

Key to recommendations and symbols:
- ✓ Included on Formulary
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Medicine name:	Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil (as fumarate) tablet (Stribild®) *Gilead Sciences Ltd*	Reason for consideration:	New combination
Indication under review:	Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®.		
SMC/ HIS reference:	SMC 887/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Stribild® was at least as effective as two other recommended antiretroviral regimens in treatment-naïve HIV-1 infected patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Stribild®. 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.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to use by HIV specialists.		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Latanoprost preservative-free eye drops (Monopost®) *Spectrum Thea Pharmaceuticals Ltd*	Reason for consideration:	New presentation
Indication under review:	For the reduction of elevated intraocular pressure in patients with open angle glaucoma and ocular hypertension.		
SMC/ HIS reference:	SMC 879/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: to use in patients who have proven sensitivity to the preservative benzalkonium chloride. SMC has previously accepted preserved latanoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent generic multi-dose eye drop preparation with preservative.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist initiation and use in patients who have proven sensitivity to the preservative benzalkonium chloride.		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Ursodeoxycholic acid tablets (Ursofalk®) *Dr Falk Pharma UK Ltd*	Reason for consideration:	New presentation
Indication under review:	For the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s). For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis.		
SMC/ HIS reference:	SMC 889/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Ursodeoxycholic acid 500mg film-coated tablets have demonstrated bioequivalence to ursodeoxycholic acid 250mg capsules. Relative costs may vary slightly depending on the pack size used.		
FND recommendation:	Ⓢ Included in the GGC Preferred List for the indication in question. Restricted to specialist initiation.		✓R
ADTC Decision 12/08/13	AGREED		

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

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

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 5: Medicines not recommended by SMC

Medicine name:	Aflibercept concentrate (Zaltrap®) *Sanofi*	Reason for consideration:	New indication
Indication under review:	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.		
SMC/ HIS reference:	SMC 878/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	In one randomised, double-blind, phase III study, aflibercept plus FOLFIRI chemotherapy regimen resulted in significantly longer overall survival compared with placebo plus FOLFIRI chemotherapy regimen. However the effect was of relatively modest clinical benefit. 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 SMC.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Medicine name:	Chloroprocaine hydrochloride (Ampres®) *Mercury Pharmaceuticals Ltd*	Reason for consideration:	New medicine
Indication under review:	Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes.		
SMC/ HIS reference:	SMC 885/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	In a small, single-centre, randomised, double-blind, controlled study spinal anaesthesia with chloroprocaine injection compared with a hyperbaric formulation of an amide-type local anaesthetic agent was associated with a faster resolution of sensory and motor block, resulting in a shorter time to meet eligibility criteria for discharge. 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:	Everolimus (Afinitor®) *Novartis Pharmaceuticals UK Limited*	Reason for consideration:	New indication
Indication under review:	Treatment of hormone receptor-positive, human epidermal growth factor type 2 (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.		
SMC/ HIS reference:	SMC 872/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	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. 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.		✘

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:	Nomegestrol acetate / estradiol (Zoely®) *Merck Sharp & Dohme Limited*	Reason for consideration:	New medicine
Indication under review:	Oral contraception.		
SMC/ HIS reference:	SMC 898/13 [Non Submission]		
Summary of advice:	Not recommended for use within 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:	Adalimumab (Humira®) *AbbVie Limited*	Reason for consideration:	New indication
Indication under review:	For the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.		
SMC/ HIS reference:	SMC 880/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: prescribing by specialists in paediatric gastroenterology. Treatment of paediatric patients with adalimumab resulted in similar clinical remission and response rates at weeks 26 and 52 to that achieved with adalimumab in severe active Crohn's disease in adults. Adalimumab has previously been accepted for use for this indication in adults with severe active Crohn's disease in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE Multiple Technology Appraisal No 187 was valid for Scotland.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use in paediatric gastroenterology.		✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Adalimumab (Humira®) subcutaneous injection *AbbVie Limited*	Reason for consideration:	Product update
Indication under review:	In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 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 2 years.		
SMC/ HIS reference:	SMC 881/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: 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 children and adolescents aged 4 to 17 years.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use within specialist rheumatology services (including those working within the network for paediatric rheumatology).		✓R
ADTC Decision 12/08/13	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: Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use in accordance with regional protocol. 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.			✓R
ADTC Decision 12/08/13	AGREED		

Medicine name:	Aprepitant (Emend®) /fosaprepitant (IVEmend®) *Merck, Sharp and Dohme*	Indication:	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy.
Reason for consideration:	New regional guidance	SMC decision:	SMC 132/04 SMC 242/06
FND recommendation, restrictions on use and comments: Acknowledge new regional guidance and amend formulary restriction as appropriate. Ⓢ Restricted to use according to regional protocol for the prevention of acute and delayed nausea and vomiting with highly emetogenic cisplatin-based chemotherapy in adults. The prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy is not recommended by SMC and remains non-Formulary. Previous regional guidance has restricted the use of aprepitant/fosaprepitant to the second line setting. SMC guidance accepts first line use for cisplatin based regimens and regional advice is that there is an unmet need for improved emetic control in patients receiving cisplatin. The CINV guideline has been updated to recommend first line use of aprepitant/fosaprepitant with all cisplatin based regimens.			
ADTC Decision 12/08/13	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