NEW DRUG RECOMMENDATIONS
OCTOBER / NOVEMBER 2013

NHS Greater Glasgow and Clyde

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

Medicine name:	Axitinib (Inlyta®) *Pfizer*	Reason for consideration:	New medicine
Indication under review:	For the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.		
SMC/ HIS reference:	SMC 855/13 [Resubmission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In a phase III, open-label study, axitinib improved progression-free survival significantly more than another targeted therapy when used after first-line sunitinib or a cytokine. There was no significant improvement in overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of axitinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.		
FND recommendation:	Ⓢ Included in the GGC Adult Formulary for the indication in question pending regional protocol.		✓R
ADTC Decision 09/12/13	AGREED *[Protocol finalised]*		

Medicine name:	Enzalutamide soft capsules (Xtandi®) *Astellas Pharma Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy.		
SMC/ HIS reference:	SMC 911/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In one randomised, double-blind, phase III clinical study, enzalutamide significantly increased overall survival compared with placebo. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of enzalutamide. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.		
FND recommendation:	Ⓢ Included in the GGC Adult Formulary for the indication in question pending regional protocol.		✓R
ADTC Decision 09/12/13	AGREED *[Protocol finalised]*		

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:	Mannitol inhaled (Bronchitol®) *Pharmaxis Pharmaceuticals Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care.		
SMC/ HIS reference:	SMC 837/13 [Resubmission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: As an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining lung function and in whom other osmotic agents are considered unsuitable. In two phase III clinical studies in patients with CF, inhaled mannitol was superior to a control treatment (a sub-therapeutic dose of inhaled mannitol) measured by absolute change in forced expiratory volume in one second (FEV_1) over 26 weeks.		
FND recommendation:	Included in the GGC Adult Formulary for the indication in question. Restricted to specialist initiation and thereafter prescribed by GPs. Restricted to use as an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining lung function and in whom other osmotic agents are considered unsuitable.		✓R
ADTC Decision 09/12/13	AGREED		

Medicine name:	Vemurafenib (Zelboraf®) *Roche Products Ltd*	Reason for consideration:	New medicine
Indication under review:	As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.		
SMC/ HIS reference:	SMC 792/12 [Resubmission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma. Vemurafenib significantly increases overall survival and progression-free survival compared with a current standard chemotherapy for patients with previously untreated unresectable stage IIIC or stage IV melanoma with V600 BRAF mutation. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of vemurafenib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower.		
FND recommendation:	Included in the GGC Adult Formulary for the indication in question restricted to first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma pending regional protocol.		✓R
ADTC Decision 09/12/13	AGREED		

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

Medicine name:	Atomoxetine capsules (Strattera®) *Eli Lilly and Company*	Reason for consideration:	New indication
Indication under review:	Treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed.		
SMC/ HIS reference:	SMC 909/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Short term studies in adults have shown that atomoxetine improves symptoms of ADHD compared to placebo. The economic case for atomoxetine has been demonstrated for a treatment duration of one year.		
FND recommendation:	Included in the GGC Adult Formulary for the indication in question. Restricted to specialist initiation.		✓R
ADTC Decision 09/12/13	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

Medicine name:	Eltrombopag film coated tablets (Revolade®) *GlaxoSmithKline*	Reason for consideration:	New indication
Indication under review:	In adult patients with chronic hepatitis C virus infection, for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.		
SMC/ HIS reference:	SMC 919/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Two double-blind, randomised, controlled studies in patients with chronic hepatitis C virus infection and thrombocytopenia demonstrated significantly higher sustained viral response rates in patients who continued treatment with eltrombopag during interferon-based antiviral therapy than in those patients whose eltrombopag treatment was discontinued on initiation of antiviral therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eltrombopag. 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 Adult Formulary for the indication in question. Restricted to specialist use.		✓R
ADTC Decision 09/12/13	AGREED		

Medicine name:	Ondansetron orodispersible films (Setofilm®) *Norgine*	Reason for consideration:	New formulation
Indication under review:	In adults: - Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy. - Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy. - Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy. - Prophylaxis and treatment of post-operative nausea and vomiting (PONV). In paediatric populations: - Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months. - Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥4 years.		
SMC/ HIS reference:	SMC 912/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing. Generic preparations of ondansetron are available at a lower cost than the proprietary products.		
FND recommendation:	Ⓢ Included in the GGC Adult Formulary (Total Formulary) and Paediatric Formulary for the indication in question. Use of this formulation is restricted to patients with an enhanced risk of aspiration or who experience difficulties in swallowing.		✓R
ADTC Decision 09/12/13	AGREED		

Key to recommendations and symbols:
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✓R Included on Formulary with restrictions
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Medicine name:	Ranibizumab (Lucentis®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment for visual impairment due to choroidal neovascularisation secondary to pathologic myopia in adults.		
SMC/ HIS reference:	SMC 907/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In patients with choroidal neovascularisation secondary to pathologic myopia, ranibizumab intravitreal injection was associated with a significant improvement in visual acuity of 8.4 Early Treatment Diabetic Retinopathy Study letters at three months compared with photodynamic therapy. 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 in NHS Scotland or a list price that is equivalent or lower		
FND recommendation:	Ⓢ Included in the GGC Adult Formulary for the indication in question. Restricted to specialist use.		✓R
ADTC Decision 09/12/13	AGREED		

Medicine name:	Saxagliptin (Onglyza®) *Bristol-Myers Squibb/AstraZeneca*	Reason for consideration:	New indication
Indication under review:	In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.		
SMC/ HIS reference:	SMC 918/13 [Full Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: as an alternative dipeptidyl peptidase-4 inhibitor option. Treatment with saxagliptin reduces glycosylated haemoglobin, HbA1c, levels significantly more than placebo when used in combination with metformin and a sulphonylurea. Indirect comparisons demonstrated similar efficacy to other dipeptidyl peptidase-4 inhibitors		
FND recommendation:	Included in the GGC Adult Formulary for the indication in question. Restricted to use in patients who are inadequately controlled on their respective maximal tolerated doses of metformin and sulphonylurea.		✓R
ADTC Decision 09/12/13	AGREED		

Medicine name:	Sodium phenylbutyrate (Pheburane®) granules Lucane Pharma	Reason for consideration:	New formulation
Indication under review:	Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.		
SMC/ HIS reference:	SMC 914/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	It is indicated in all patients with neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonaemic encephalopathy. Sodium phenylbutyrate granules (Pheburane®) provide an alternative to sodium phenylbutyrate tablets at no additional cost but are more expensive than an existing brand of sodium phenylbutyrate granules		
FND recommendation:	Ⓢ Included in the GGC Adult and Paediatric Formularies for the indication in question. Available granule formulations are not dose equivalent and are not interchangeable.		✓R
ADTC Decision 09/12/13	AGREED – subject to the addition of "..and should be prescribed by brand name to avoid confusion".		

Key to recommendations and symbols:
- ✓ Included on Formulary
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Medicine name:	Vildagliptin (Galvus®) *Norvatis Europharm Limited*	Reason for consideration:	New indication
Indication under review:	Treatment of type 2 diabetes mellitus in adults as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.		
SMC/ HIS reference:	SMC 875/13 [Full Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: as an alternative dipeptidyl peptidase-4 inhibitor option. Treatment with vildagliptin reduces HbA1c levels significantly more than placebo when used in combination with metformin and a sulphonylurea. A Bayesian network meta-analysis suggested similar efficacy to another dipeptidyl peptidase-4 inhibitor.		
FND recommendation:	Included in the GGC Adult Formulary for the indication in question. Restricted to use in patients who are inadequately controlled on their respective maximal tolerated doses of metformin and sulphonylurea.		✓R
ADTC Decision 09/12/13	AGREED		

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

Section 4: Medicines not recommended by SMC

Medicine name:	Azelastine hydrochloride plus fluticasone propionate (Dymista®) *Meda Pharmaceuticals*	Reason for consideration:	New combination
Indication under review:	For the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.		
SMC/ HIS reference:	SMC 921/13 [Abbreviated Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	The combined azelastine and fluticasone nasal spray is significantly more expensive than the components administered separately.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✗

Medicine name:	Botulinum toxin type A (Botox®) *Allergan Ltd*	Reason for consideration:	New indication
Indication under review:	Management of bladder dysfunctions in adult patients with overactive bladder with symptoms of urinary incontinence, urgency and frequency who are not adequately managed with anticholinergics.		
SMC/ HIS reference:	SMC 931/13 [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. The sponsor company plans to make a submission to SMC in March 2014.		
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:	Bosutinib film coated tablets (Bosulif®) *Pfizer Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of adult patients with chronic phase, accelerated phase, and blast phase Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.		
SMC/ HIS reference:	SMC 910/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	Evidence of efficacy for the indication under review comes from a subgroup of 52 patients who represent "unmet medical need" in the pivotal study, in which the full population included 546 patients with chronic, accelerated and blast phase imatinib pre-treated Ph^+ CML. The submitting company did not present a sufficiently robust clinical and economic analysis and in addition their justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✗

Medicine name:	Canakinumab (Ilaris®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged two years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate.		
SMC/ HIS reference:	SMC 926/13 [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 Paediatric Formulary for the indication in question.		✗

Medicine name:	Cefuroxime sodium (Aprokam®) *Spectrum thea Pharmaceuticals Limited*	Reason for consideration:	New presentation
Indication under review:	Antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery.		
SMC/ HIS reference:	SMC 932/13 [Non Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
Governance issues:	Please note: Surgery & Anaesthetics Directorate have highlighted the need to use this preparation. To date they had been using an unlicensed preparation and there have been recent problems regarding quality, and the alternative involves multiple manipulations in theatre.		
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.		✗

Medicine name:	Imiquimod (Zyclara®) *Meda Pharmacueticals*	Reason for consideration:	New presentation
Indication under review:	Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.		
SMC/ HIS reference:	SMC 934/13 [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.		✗

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:	Lapatinib (Tyverb®) *GlaxoSmithKline*	Reason for consideration:	New indication
Indication under review:	Treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2) in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.		
SMC/ HIS reference:	SMC 925/13 [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.		✗

Medicine name:	Micronized progesterone (Utrogestan®) *Malborough Pharmaceuticals Ltd*	Reason for consideration:	New presentation
Indication under review:	Supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.		
SMC/ HIS reference:	SMC 935/13 [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 5: Medicines accepted by SMC – Consideration in GGC Paediatric Formulary only

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