NEW DRUG RECOMMENDATIONS
APRIL 2013

NHS Greater Glasgow and Clyde

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

Medicine name:	Ingenol mebutate gel (Picato®) *Leo Laboratories*	Reason for consideration:	New medicine
Indication under review:	Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.		
SMC/ HIS reference:	SMC 851/13 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In four randomised, double-blind, phase III studies, a significantly greater proportion of adults with actinic keratosis (AK) achieved complete clearance when treated with ingenol mebutate gel compared with vehicle control		
FND recommendation:	Included in the GGC Total Formulary for the indication in question.		✓
ADTC Decision 08/04/13	AGREED		

Medicine name:	Tegafur / gimeracil / oteracil hard capsules (Teysuno®) *Nordic Pharma Ltd*	Reason for consideration:	New medicine (combination)
Indication under review:	in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.		
SMC/ HIS reference:	SMC 802/12 [Full Submission] [Deferred Decision]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: tegafur/gimeracil/oteracil is restricted to use in patients with advanced gastric cancer who are unsuitable for an anthracycline, fluorouracil and platinum triplet first-line regimen. In a multicentre, randomised, open-label clinical study in adult patients with advanced gastric cancer, tegafur/gimeracil/oteracil in combination with cisplatin was non-inferior to an intravenous fluoropyrimidine plus cisplatin with respect to overall survival.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use only in accordance with regional protocol.		✓R
ADTC Decision 08/04/13	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 infusion (Orencia®) *Bristol Myers Squibb Pharmaceuticals Ltd*	Reason for consideration:	New indication
Indication under review:	In combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients 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 719/11 [Resubmission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: abatacept is restricted for use in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart. In combination with methotrexate, abatacept reduced the progression of joint damage and improved physical function more than placebo in patients with moderate to severe rheumatoid arthritis who responded inadequately to previous therapy with methotrexate alone. 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 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 in patients with active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart.		✓R
ADTC Decision 08/04/13	AGREED		

Medicine name:	Adalimumab injection (Humira®) *AbbVie Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of adults with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).		
SMC/ HIS reference:	SMC 858/13 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Adalimumab, compared to placebo, improves symptoms of severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults. Adalimumab should be prescribed in accordance with Assessment in Spondyloarthritis International Society (ASAS) guidance.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. To be used in accordance with ASAS guidance		✓R
ADTC Decision 08/04/13	AGREED		

Medicine name:	Bimatoprost single-dose eye drops (Lumigan UD®) *Allergan Ltd*	Reason for consideration:	New presentation
Indication under review:	Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers).		
SMC/ HIS reference:	SMC 839/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in 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 bimatoprost eye-drops for use in NHS Scotland. This preparation is substantially more expensive than the equivalent multi-dose eye drop preparation with preservative.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to use only in patients who have proven sensitivity to the preservative benzalkonium chloride.		✓R
ADTC Decision 08/04/13	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:	Darunavir oral suspension (Prezista®) *Janssen-Cilag Ltd*	Reason for consideration:	New formulation
Indication under review:	Co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight.		
SMC/ HIS reference:	SMC 861/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV. Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to use by HIV specialists.		✓R
ADTC Decision 08/04/13	AGREED		

Medicine name:	Insulin glargine (Lantus®, Clicstar®, Lantus® Solostar®) *Sanofi*	Reason for consideration:	New indication (paediatric extension)
Indication under review:	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above		
SMC/ HIS reference:	SMC 860/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: patients in whom treatment with an insulin analogue is appropriate. Its use should be targeted on patients with Type I diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections. The pre-filled pen has previously been accepted for restricted use in patients from the age of 6 years and above.		
FND recommendation:	Included in the GGC Preferred List for the indication in question. Restricted to patients with type 1 diabetes who are at risk of or experience unacceptable frequency and/or severity of nocturnal hypoglycaemia on attempting to achieve better hypoglycaemic control during treatment with established insulins. It is also acceptable as a once daily insulin therapy for patients who require carer administration of their insulin. In patients with type 2 diabetes it should be restricted to those who suffer from recurrent episodes of hypoglycemia or require assistance with their insulin injections.		✓R
ADTC Decision 08/04/13	AGREED		

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

Medicine name:	Rivaroxaban tablets (Xarelto®) *Bayer PLC*	Reason for consideration:	New indication
Indication under review:	Treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults.		
SMC/ HIS reference:	SMC 852/13 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Rivaroxaban was non-inferior to standard therapy including a low molecular weight heparin and a vitamin K antagonist for the treatment of PE and the prevention of recurrence of DVT or PE. Duration of treatment was 3, 6 or 12 months at the discretion of the treating physician. 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:	Included in the GGC Total Formulary for the indication in question. Restricted to use in accordance with local guidance for patients requiring anticoagulation where the intended duration of treatment is 3 to 6 months. Where indefinite duration is indicated, then the treatment of choice should be a low molecular weight heparin followed by warfarin.		✓R
ADTC Decision 08/04/13	AGREED		

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

Medicine name:	Ulipristal acetate tablets (Esmya®) *PregLem Ltd*	Reason for consideration:	New indication
Indication under review:	Pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months.		
SMC/ HIS reference:	SMC 834/13 [Full Submission] [Deferred Decision]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Ulipristal was superior to placebo and non-inferior to a gonadotrophin releasing hormone (GnRH) agonist for reducing uterine bleeding in pre-operative women with uterine fibroids and excessive bleeding		
FND recommendation:	Not included in the GGC Total Formulary for the indication in question because clinicians do not support the Formulary inclusion. Alternative medicines are available in section 6.7.2 of the Formulary.		✘
ADTC Decision 08/04/13	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 4: Medicines accepted by SMC – Not included pending protocol/consultation

Medicine name:	Aflibercept intravitreal injection (Eylea®) *Bayer PLC*	Reason for consideration:	New medicine
Indication under review:	Treatment of neovascular (wet) age-related macular degeneration in adults.		
SMC/ HIS reference:	SMC 857/13 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In two pivotal randomised controlled studies the non-inferiority of aflibercept versus monthly injections of another anti-VEGF treatment was demonstrated for the primary endpoint; proportion of patients who maintained vision at week 52. The economic analysis submitted by the company related to the use of aflibercept in patients with wet AMD who have not previously been treated with anti-VEGF therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of aflibercept. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question pending protocol.		✘
ADTC Decision 08/04/13	AGREED		

Medicine name:	Ipilimumab infusion (Yervoy®) *Bristol Myers Squibb Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy.		
SMC/ HIS reference:	SMC 779/12 [Resubmission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Ipilimumab demonstrated a survival benefit over an investigational glycoprotein100 peptide vaccine in previously treated patients with advanced melanoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ipilumumab. 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 for the indication in question pending protocol.		✘
ADTC Decision 08/04/13	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:	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]		
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:	Not included in the GGC Adult Formulary for the indication in question pending protocol.		✘
ADTC Decision 08/04/13	AGREED		

Section 5: Medicines not recommended by SMC

Medicine name:	Axitinib tablets (Inlyta®) *Pfizer*	Reason for consideration:	New medicine
Indication under review:	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 [Full Submission]		
Summary of advice:	Not recommended for use in 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. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance, 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:	Bevacizumab (Avastin®) *Roche Products Ltd*	Reason for consideration:	New indication
Indication under review:	Bevacizumab, in combination with carboplatin and gemcitabine, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelian ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents		
SMC/ HIS reference:	SMC 853/13 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	A randomised double-blind, placebo-controlled, phase III study demonstrated a significant improvement in progression-free survival (PFS) in patients with platinum-sensitive recurrent ovarian cancer (ROC) treated with bevacizumab in combination with gemcitabine and carboplatin, compared with gemcitabine and carboplatin alone. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC		
FND recommendation:	Not 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:	Botulinum toxin type A (Botox®) *Allergan Ltd*	Reason for consideration:	New indication
Indication under review:	Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).		
SMC/ HIS reference:	SMC 692/11 [Resubmission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	In pooled analysis of the two pivotal phase III studies, botulinum toxin type A significantly reduced the frequency of headache days compared with placebo. 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:	Deferasirox dispersible tablets (Exjade®) *Novartis Pharmaceuticals UK Ltd.*	Reason for consideration:	New indication
Indication under review:	Treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.		
SMC/ HIS reference:	SMC 866/13 [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.		✘

Medicine name:	Insulin degludec (Tresiba®) *Novo Nordisk*	Reason for consideration:	New medicine
Indication under review:	Treatment of diabetes mellitus in adults.		
SMC/ HIS reference:	SMC 856/13 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	Insulin degludec is non-inferior to other long-acting insulin analogues for treatment of type 1 and type 2 diabetes mellitus in adults assessed via glycosylated haemoglobin (HbA1c) and it is superior to a dipeptidylpeptidase-4 inhibitor in type 2 diabetes mellitus. 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:	Ruxolitinib tablets (Jakavi®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.		
SMC/ HIS reference:	SMC 867/13 [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.		✘

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:	Timothy grass pollen allergen (Grazax®) *ALK-Albello Ltd*	Reason for consideration:	New indication
Indication under review:	Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.		
SMC/ HIS reference:	SMC 868/13 [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:	Infliximab (Remicade®) *Merck Sharp & Dohme Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.		
SMC/ HIS reference:	SMC 854/13 [Full Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory. Open-label, uncontrolled data indicate that infliximab induces remission of moderate to severe active ulcerative colitis in paediatric patients.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory.		✓R
ADTC Decision 08/04/13	AGREED		

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

Medicine name:	Liquid paraffin 11% cream (Zerobase®) *Thornton & Ross*	Indication:	Emollient cream
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.			✓
ADTC Decision 08/04/13	AGREED		

Medicine name:	Light Liquid paraffin 12.6% cream (Zerocream®) *Thornton & Ross*	Indication:	Emollient cream
Reason for consideration:	Formulary Appeal	SMC decision:	Not applicable
FND recommendation, restrictions on use and comments: Included in the Total Formulary for the indication in question.			✓
ADTC Decision 08/04/13	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:	Light Liquid paraffin 40% ointment (Zeroderm®) *Thornton & Ross*	Indication:	Emollient ointment
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.			✓
ADTC Decision 08/04/13	AGREED		

Medicine name:	Coal tar 6% and lecithin 0.4% cream (Psoriderm®) *Dermal*	Indication:	Psoriasis of the scalp
Reason for consideration:	Formulary housekeeping	SMC decision:	Not applicable
FND recommendation, restrictions on use and comments: Included in the Preferred List for the indication in question. This preparation displaces Alphosyl HC® from the GGC Adult Formulary which has been discontinued.			✓
ADTC Decision 08/04/13	AGREED		

Medicine name:	Imiquimiod cream (Aldara®) *Meda*	Indication:	The treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients
Reason for consideration:	Formulary housekeeping	SMC decision:	SMC 385/07 [Resubmission] Accepted for restricted use in NHS Scotland
FND recommendation, restrictions on use and comments: Ⓢ Included in the Total Formulary for the indication in question. Restricted to specialist initiation. This preparation is currently specialist use only for this indication, whereas another indication for the same preparation is specialist initiation and other preparations for the same indication are also specialist initiation. This revision of the Formulary status allows a more suitable formulary position considering the other therapeutic options available.			✓R
ADTC Decision 08/04/13	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