NEW DRUG RECOMMENDATIONS
MARCH 2012

NHS Greater Glasgow and Clyde

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

Medicine name:	**Capsaicin cutaneous patch (Qutenza®)** *Astellas Pharma UK Limited*	Reason for consideration:	**New formulation**
Indication under review:	**Treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.**		
SMC/ HIS reference:	**SMC 673/11 [Deferred Decision]**		
Summary of advice:	**Accepted for restricted use within NHS Scotland**		
SMC/HIS restriction and comments:	The SMC restriction is for the treatment of adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first and second-line treatments. Treatment should be under the supervision of a specialist in pain management. Evidence was presented for patients with PHN only. Capsaicin patch significantly reduced pain scores compared to a low-concentration control patch in three clinical studies. The manufacturer did not submit data on the use of capsaicin patch in other neuropathies therefore SMC cannot recommend its use in these patient groups.		
FND recommendation:	**Ⓢ Included in the Total Formulary for post herpetic neuralgia. Restricted to specialist use in line with prescribing guidance.**		✓R
ADTC Decision 16/04/12	AGREED		

Medicine name:	**Rivaroxaban (Xarelto®)** *Bayer PLC*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.**		
SMC/ HIS reference:	**SMC 755/12 [Full Submission] [Deferred Decision]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Rivaroxaban has been shown to be non-inferior to standard anticoagulant therapy including a low molecular weight heparin in combination with a vitamin K antagonist for the treatment of proximal DVT and prevention of recurrence. Experience with rivaroxaban in this indication for more than 12 months is limited therefore the cost-effectiveness of indefinite treatment has not been demonstrated.		
FND recommendation:	**Included in the Total Formulary for the indication in question.** **Restricted to use in the following patient groups only where the intended duration of treatment is for 3-6 months** – **Patients who are allergic or intolerant to warfarin or in patients** – **Patients who have poor INR control despite evidence that they are complying with warfarin therapy** **Where indefinite duration is indicated, then the treatment choice should be LMWH/warfarin.**		✓R
ADTC Decision 16/04/12	**Pending clarification of the protocol, this medicine should be included in the Total Formulary for the indication in question restricted to use in patients groups where the intended duration of treatment was for 3-6 months.**		✓R

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:	**Bupivacaine and Fentanyl (as citrate) (Bufyl®)** *Goldshield Pharmaceuticals Ltd*	Reason for consideration:	**New presentation**
Indication under review:	**Epidural analgesia to relieve pain during labour and to control post operative pain.**		
SMC/ HIS reference:	**SMC 761/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	For patients in whom the combination of bupivacaine and fentanyl is an appropriate choice of therapy, Bufyl® provides two fixed-dose, pre-mixed preparations.		
FND recommendation:	**Ⓢ Included in the Total Formulary for the indication in question.**		✓R
ADTC Decision 16/04/12	**AGREED**		

Medicine name:	**Dabigatran (Pradaxa®)** *Boehringer Ingelheim Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Prevention of stroke and systemic embolism in adult patients with non-valvular AF with one or more risk factors. See SMC review for full details.**		
SMC/ HIS reference:	**SMC 672/11 [Full Submission] [Deferred Decision]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Dabigatran etexilate was at least as effective as standard oral anticoagulation at preventing stroke or systemic embolism in one large, open-label study in patients with atrial fibrillation and at least one risk factor for stroke. This was not associated with an increased risk of major bleeding. The economic case made supports the use of the proposed sequenced dosing regimen (whereby the dose is reduced from 150mg twice daily to 110mg twice daily in patients aged ≥ 80 years). This applies whether the alternative treatment is warfarin, aspirin or 'no treatment' (i.e. neither warfarin nor aspirin).		
ADTC Decision 16/04/12	**This medicine had the Formulary restriction confirmed for the indication in question in light of further consultation with the MCN. Use is restricted to patients currently receiving warfarin who have poor INR control despite evidence that they are complying, patients with allergy or intolerable side effects from coumarin anticoagulants or for patients for whom warfarin has been clinically excluded as a therapeutic option but anticoagulation is deemed safe and appropriate. Preference over warfarin for practical rather than clinical reasons remains non-Formulary. Further information can be found in the National Consensus Statement on the NHS HIS website or local guidance**		✓R

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:	**Rivaroxaban (Xarelto®)** *Bayer PLC*	Reason for consideration: **New indication**
Indication under review:	**The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.**	
SMC/ HIS reference:	**SMC 756/12 [Full Submission] [Deferred Decision]**	
Summary of advice:	**Accepted for restricted use in NHS Scotland**	
SMC/HIS restriction and comments:	SMC restriction: Rivaroxaban is accepted for use in patients who have poor INR control despite evidence that they are complying with a coumarin anticoagulant and in patients who are allergic to or unable to tolerate coumarin anticoagulants. Rivaroxaban was non-inferior to standard oral anticoagulation at preventing stroke or systemic embolism in one large, double-blind study in patients with atrial fibrillation and moderate to high risk of stroke. This was not associated with a significantly increased risk of major or non-major clinically relevant bleeding. The submitting company made an economic case for rivaroxaban use in the restricted patient population described above.	
ADTC Decision 16/04/12	**This medicine had the Formulary restriction confirmed for the indication in question in light of further consultation with the MCN. Use is restricted to patients currently receiving warfarin who have poor INR control despite evidence that they are complying, patients with allergy or intolerable side effects from coumarin anticoagulants or for patients for whom warfarin has been clinically excluded as a therapeutic option but anticoagulation is deemed safe and appropriate. Preference over warfarin for practical rather than clinical reasons remains non-Formulary. Further information can be found in the National Consensus Statement on the NHS HIS website or local guidance**	✓R

Medicine name:	**Midazolam (Buccolam®)** *ViroPharma Ltd*	Reason for consideration: **New formulation**
Indication under review:	**Treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years).**	
SMC/ HIS reference:	**SMC 757/12 [Full Submission]**	
Summary of advice:	**Accepted for use in NHS Scotland**	
SMC/HIS restriction and comments:	Midazolam given via the buccal route was considered at least non-inferior to rectally administered benzodiazepine in terminating acute prolonged seizures. The economic case was demonstrated for midazolam compared to rectal diazepam.	
FND recommendation:	**Not included in the GGC Formulary pending specialist consultation for general advice or protocol development.** **This preparation is currently being considered by NHSGGC as any potential change will require careful implementation with training for all involved in the prescribing, dispensing and administration of the buccal midazolam since Epistatus® (the unlicensed product currently in use in paediatrics) is twice the strength of buccolam.**	✗
ADTC Decision 16/04/12	**Included in the Total Formulary for the indication in question. It should be noted that many existing patients will be using an alternative unlicensed preparation (Epistatus®), and due to the difference in strength and associated risks, any change of treatment to existing patients would require careful management.**	✓R

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 3: Medicines accepted by SMC – Not included in Formulary

Medicine name:	**Atorvastatin chewable tablets (Lipitor®)** *Pfizer Ltd*	Reason for consideration:	**New formulation**
Indication under review:	**Treatment of hypercholesterolaemia and primary prevention of cardiovascular events (see SMC advice for full list of indications)**		
SMC/ HIS reference:	**SMC 766/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Atorvastatin chewable tablets have demonstrated bioequivalence to atorvastatin film-coated tablets (Lipitor®) and are available at an equivalent cost. However less expensive generic preparations of atorvastatin tablets are expected to become available in the near future.		
FND recommendation:	**Not included in the GGC Formulary because the ADTC considered - that the medicine does not represent sufficient added benefit to other comparator medicines already available on the Formulary.**		✘
ADTC Decision 16/04/12	AGREED		

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

Medicine name:	**Icatibant acetate (Firazyr®)** *Shire Human Genetic Therapies*	Reason for consideration:	**New medicine**
Indication under review:	**Symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency).**		
SMC/ HIS reference:	**SMC 476/08 [Resubmission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Icatibant treatment resulted in symptom relief in patients suffering acute abdominal, cutaneous and/or laryngeal attacks of hereditary angioedema. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of icatibant. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.		
FND recommendation:	**Not included in the GGC Formulary pending protocol.**		✘
ADTC Decision 16/04/12	**AGREED**		

Medicine name:	**Imatinib (Glivec®)** *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Adjuvant treatment of adult patients who are at significant risk of relapse following resection of a KIT (CD117) positive gastrointestinal stromal tumour (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.**		
SMC/ HIS reference:	**SMC 584/-90 [2nd Resubmission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	Imatinib is restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria). Adjuvant imatinib therapy given for a period of three years compared to one year, significantly improved the recurrence free survival in adult patients at significant risk of relapse following resection of GIST. The clinical and cost-effectiveness of three years adjuvant imatinib treatment was demonstrated.		
FND recommendation:	**Not included in the GGC Formulary for the indication in question pending protocol (Regional Cancer Advisory Group).**		✘
ADTC Decision 16/04/12	**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:	**Bee or wasp venom immunotherapy (Pharmalgen)** *ALK-Abello*	Indication:	Treatment of IgE-mediated bee and wasp venom allergy in people with severe systemic reaction to bee or wasp venom
Reason for consideration:	**NICE MTA246**	SMC decision:	**N/A**
FND recommendation, restrictions on use and comments: **Not included pending completion of the consultation exercise.**			✘
ADTC Decision 16/04/12	**AGREED**		

Section 5: Medicines not recommended by SMC

Medicine name:	**Abiraterone (Zytiga®)** *Janssen*	Reason for consideration:	**New medicine**
Indication under review:	**With prednisone or prednisolone for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.**		
SMC/ HIS reference:	**SMC 764/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Abiraterone plus prednisone was associated with significantly improved overall survival compared with placebo plus prednisone in patients with mCRPC previously treated with docetaxel. The submitting company's justification of the treatment's costs in relation to its health benefits was not sufficient to gain acceptance by SMC. 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 Formulary.**		✘

Medicine name:	**Asenapine (Sycrest®)** *Lundbeck Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of moderate to severe manic episodes associated with bipolar 1 disorder in adults.**		
SMC/ HIS reference:	**SMC 762/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Asenapine when used as monotherapy demonstrated superior efficacy to placebo in reducing manic symptoms as measured using the Young Mania Rating Score at three weeks with maintenance of effect at 12 weeks. In addition, asenapine in combination with lithium or valproate demonstrated superior efficacy to lithium or valproate monotherapy. There are no direct comparative data when asenapine is used as add-on treatment. Indirect comparisons with other second generation antipsychotic agents used as monotherapy and as adjunctive therapy suggested equivalent efficacy. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.		
FND recommendation:	**Not included in the GGC Formulary.**		✘

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:	**Belimumab (Benlysta®)** *Roche Products Limited*	Reason for consideration:	**New medicine**
Indication under review:	**Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.**		
SMC/ HIS reference:	**SMC 775/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Belimumab, in addition to standard of care, modestly improved disease control in patients with SLE in two phase III studies. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and, in addition, the submitting company did not present a sufficiently robust economic case to gain acceptance by SMC.		
FND recommendation:	**Not included in the GGC Formulary.**		✘

Medicine name:	**Catumazomab (Removab®)** *Fresenius Biotech GmbH*	Reason for consideration:	**New medicine**
Indication under review:	**Intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible.**		
SMC/ HIS reference:	**SMC 788/12 [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 Formulary.**		✘

Medicine name:	**Everolimus (Votubia®)** *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.**		
SMC/ HIS reference:	**SMC 787/12 [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 Formulary.**		✘

Medicine name:	**Fampridine (Fampyra®)** *Biogen Idec Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Improvement of walking in adult patients with multiple sclerosis with walking disability.**		
SMC/ HIS reference:	**SMC 789/12 [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 Formulary.**		✘

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:	**Fingolimod (as hydrochloride) (Gilenya®)** *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups:** – **Patients with high disease activity despite treatment with a beta-interferon.** **or** – **Patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with one or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.**		
SMC/ HIS reference:	**SMC 763/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Fingolimod reduced the annualised relapse rate significantly more than a beta-interferon in patients with clinically active RRMS. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.		
FND recommendation:	**Not included in the GGC Formulary.**		✘

Medicine name:	**Tocilizumab (RoActemra®)** *Roche Products Limited*	Reason for consideration:	**New indication**
Indication under review:	**Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.**		
SMC/ HIS reference:	**SMC 774/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	In a phase III study of adults with moderate to severe RA for at least three months, tocilizumab monotherapy was found to be superior to methotrexate in terms of ACR20 response rate. The submitting company did not present sufficiently robust clinical and economic analysis to gain acceptance by SMC.		
FND recommendation:	**Not included in the GGC Formulary for the indication in question.**		✘

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

No entries in this section.

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

Medicine name:	**Acitretin (Neotigason®) capsules** *Actavis UK Ltd*	Indication:	Severe extensive psoriasis which is resistant to other forms of therapy, Palmo-plantar pustular psoriasis, severe congenital ichthyosis and severe Darier's disease (keratosis follicularis).
Reason for consideration:	**Formulary Appeal**	SMC decision:	**N/A**
FND recommendation, restrictions on use and comments: **Appeal not upheld. However, should agreement regarding service delivery be met, we would reconsider the Formulary status to enable a transfer of care.**			✓R
ADTC Decision 16/04/12	**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