NEW DRUG RECOMMENDATIONS
JULY 2012

NHS Greater Glasgow and Clyde

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

Medicine name:	**Azacitidine injection (Vidaza®)** *Celgene Ltd*	Reason for consideration:	**New Medicine**
Indication under review:	**For treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (SCT) with intermediate-2 and high-risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).**		
SMC/ HIS reference:	**SMC 589/09 [Resubmission] [Deferred Decision]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Azacitidine therapy produced a significant increase in overall survival compared with conventional care regimens in previously untreated higher-risk MDS patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of azacitidine. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.		
FND recommendation:	**Included in the Total Formulary for the indication in question restricted to use in accordance with regional protocol which excludes routine use in chronic myelomonocytic leukaemia (CMML.). Contingent upon PAS.**		✓R
ADTC Decision 13/08/12	**AGREED**		

Medicine name:	**Ticagrelor (Brilique®)** *AstraZeneca*	Reason for consideration:	**New Medicine**
Indication under review:	**Co-administered with aspirin, for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (unstable angina, non ST elevation myocardial infarction [NSTEMI] or ST elevation myocardial infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).**		
SMC/ HIS reference:	**SMC 699/11 [Full Submission] [Deferred Decision]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	As dual therapy with aspirin, ticagrelor demonstrated a significant reduction in ischaemic events compared with another antiplatelet drug without significantly increasing the incidence of study-defined major bleeding. Alternative treatments are available at a lower drug acquisition cost.		
FND recommendation:	**Included in the Total Formulary for the indication in question for only patients who are either intolerant to clopidogrel or have a stent thrombosis on clopidogrel. Use in other patient groups currently remains non-Formulary until regional / national position is clarified.**		✓R
ADTC Decision 13/08/12	**Included the Total Formulary for the indication in question restricted to specialist initiation only for patients who are either allergic or intolerant to clopidogrel or have a stent thrombosis on clopidogrel. Use in other patient groups currently remains non-Formulary until the regional/national position is clarified.**		✓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:	**Tadalafil (Adcirca®)** *Eli Lilly and Company Limited*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of adults with pulmonary arterial hypertension (PAH) classified as World Health Organisation functional class (WHO-FC) II and III, to improve exercise capacity.**		
SMC/ HIS reference:	**SMC 710/11 [Full Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: To initiation by specialists working in the Scottish Pulmonary Vascular Unit or similar specialists. Tadalafil demonstrated statistically significant improvement in 6 minute walking distance (6MWD) compared with placebo in patients with PAH, WHO-FC II or III. Approximately half of the study patients were receiving a concomitant endothelin receptor antagonist. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tadalafil. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.		
FND recommendation:	**Included on the Total Formulary for the indication in question restricted to initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit or similar specialists.**		✓R
ADTC Decision 13/08/12	**AGREED**		

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

Medicine name:	**Golimumab pre-filled syringe (Simponi®)** *Merck Sharp & Dohme Limited*	Reason for consideration:	**New indication**
Indication under review:	**Alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.**		
SMC/ HIS reference:	**SMC 674/11 [Resubmission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: golimumab is restricted to use in patients whose disease has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is also restricted to use at a dose of 50mg only. Golimumab has demonstrated efficacy when compared with placebo in patients with active psoriatic arthritis who have had an inadequate response to DMARDs or non-steroidal anti-inflammatory drugs (NSAIDs). The economic case was demonstrated for golimumab when used at a dose of 50mg. The economic case was not demonstrated for the 100mg dose of golimumab.		
FND recommendation:	**Included on the Total Formulary for the indication in question restricted to use in patients whose disease has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination. It is also restricted to use at a dose of 50mg only.**		✓R
ADTC Decision 13/08/12	**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:	**Nilotinib 150mg hard capsules (Tasigna®)** *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	**New indication**
Indication under review:	**For the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase.**		
SMC/ HIS reference:	**SMC 709/11 [Full Submission] [Deferred Decision]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	First-line treatment with nilotinib in newly diagnosed patients has resulted in significantly higher molecular and cytogenetic response rates compared to the standard tyrosine kinase inhibitor. Further longer term follow-up data are needed to confirm the duration of this response and assess the impact on disease progression and overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nilotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.		
FND recommendation:	**Included on the Total Formulary for the indication in question restricted to use in accordance with regional protocol. Contingent upon PAS.**		✓R
ADTC Decision 13/08/12	**AGREED**		

Medicine name:	**Eplerenone (Inspra®)** *Pfizer Ltd*	Reason for consideration:	**New indication**
Indication under review:	**In addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%).**		
SMC/ HIS reference:	**SMC 793/12 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	In the pivotal phase IIIb study, addition of eplerenone to standard optimal therapy significantly reduced the composite of death from cardiovascular causes or hospitalisation for heart failure (primary outcome) and both the risk of cardiovascular death and the risk of hospitalisation (secondary outcomes) in patients with mild heart failure (NYHA class II) and LVEF ≤30%.		
FND recommendation:	**Included on the Total Formulary for the indication in question restricted to consultant initiation only for use in patients intolerant to spironolactone.**		✓R
ADTC Decision 13/08/12	**Included on the Total Formulary for the indication in question restricted to initiation by prescribers working with specialised heart failure teams only for use in patients intolerant to spironolactone.**		✓R

Medicine name:	**Rufinamide 40mg/mL oral suspension (Inovelon®)** *Eisai Ltd*	Reason for consideration:	**New formulation**
Indication under review:	**Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older.**		
SMC/ HIS reference:	**SMC 795/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs. Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. The oral suspension is bioequivalent to the tablets and provides an alternative formulation for patients who have difficulty swallowing. Depending on the dose it may be more expensive than the tablets but any overall budget impact is likely to be small.		
FND recommendation:	**Included on the Total Formulary for the indication in question restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.**		✓R
ADTC Decision 13/08/12	**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:	**Mercaptopurine 20mg/mL oral suspension (Xaluprine®)** *Nova Laboratories Limited*	Reason for consideration:	**New formulation**
Indication under review:	**For the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children.**		
SMC/ HIS reference:	**SMC 798/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Mercaptopurine dosing is governed by cautiously monitoring haematotoxicity. The oral suspension and tablet formulations are not bioequivalent in terms of peak plasma concentrations and therefore careful haematological monitoring of the patient is advised on switching formulations. Mercaptopurine oral suspension is more expensive than the tablet formulation.		
FND recommendation:	**Ⓢ Included in the Total Formulary for the indication in question.**		✓R
ADTC Decision 13/08/12	**AGREED**		

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

No entries are include in this section

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

Medicine name:	**Abiraterone Acetate (Zytiga®)** *Janssen-Cilag Ltd*	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 [Resubmission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen. Abiraterone plus prednisone was associated with significantly improved overall survival compared with placebo plus prednisone in patients with mCRPC previously treated with docetaxel. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone. 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 (Regional Cancer Advisory Group).**		✘
ADTC Decision 13/08/12	**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:	**Fidaxomicin (Dificlir®)** *Astellas Pharma Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of adults with *Clostridium difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD).**		
SMC/ HIS reference:	**SMC 791/12 [Full Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: Treatment of adults with a first CDI recurrence only on the advice of local microbiologists or specialists in infectious diseases. Fidaxomicin demonstrated non-inferiority to another antibiotic in the clinical cure of *Clostridium difficile* infection and superiority in reducing recurrence. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC for first-line use in adults with severe CDI.		
FND recommendation:	**Ⓢ Included on the Total Formulary for the indication in question restricted to use in adults with a second relapse before pulsed/tapered vancomycin on microbiological/ infectious disease physician advice.**		✓R
ADTC Decision 13/08/12	**Not included in the GGC Adult Formulary for the indication in question pending consultation with the Antimicrobial Utilisation Sub-Committee of final positioning within the protocol.**		✗

Section 5: Medicines not recommended by SMC

Medicine name:	**Amifampridine 10mg tablet, as phosphate (Firdapse®)** *BioMarin UK Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.**		
SMC/ HIS reference:	**SMC 660/10 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	There are no clinical data for amifampridine phosphate and efficacy has been extrapolated from studies of amifampridine base (3,4-diaminopyridine), to which amifampridine phosphate has been accepted to be bioequivalent by the European Medicines Agency. In randomised controlled studies in patients with LEMS, 3,4-diaminopyridine treatment was associated with greater improvement in muscle strength and neuromuscular transmission than placebo. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the 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:	**Thiotepa powder (Tepadina®)** *Adienne S.r.l.*	Reason for consideration:	**New indication**
Indication under review:	**In combination with other chemotherapy medicinal products:** **1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients;** **2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.**		
SMC/ HIS reference:	**SMC 790/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	Two uncontrolled, non-randomised studies including patients with advanced non-Hodgkin's lymphoma or Hodgkin's disease have reported data for non-relapse mortality and overall survival. The submitting company did not present sufficiently robust clinical and economic analyses 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
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Medicine name:	**Adalimumab Prefilled Pen (Humira®)** *Abbott Laboratories Limited*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.**		
SMC/ HIS reference:	**SMC 800/12 [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.**		✘

Medicine name:	**Azilsartan Medoxomil (Edarbi®)** *Takeda*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of essential hypertension in adults**		
SMC/ HIS reference:	**SMC 803/12 [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.**		✘

Medicine name:	**Azithromycin Dihydrate (Azyter®)** *Spectrum Thea Pharmaceuticals*	Reason for consideration:	**New indication**
Indication under review:	**Local antibacterial treatment of conjunctivitis caused by susceptible strains:** **- Purulent bacterial conjunctivitis,** **- Trachomatous conjunctivitis caused by Chlamydia trachomatis.**		
SMC/ HIS reference:	**SMC 804/12 [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.**		✘

Medicine name:	**Rifaximin (Xifaxanta®)** *Norgine Limited*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of travellers' diarrhoea that is not associated with any of: Fever ; Bloody diarrhoea ; Eight or more unformed stools in the previous 24 h; Occult blood or leucocytes in the stool.**		
SMC/ HIS reference:	**SMC 808/12 [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.**		✘

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

Medicine name:	**Pegylated interferon alfa-2b pre-filled pen (ViraferonPegol®)** *MSD Ltd*	Reason for consideration:	**New indication**
Indication under review:	**In a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA.**		
SMC/ HIS reference:	**SMC 794/12 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	This treatment involves a once weekly injection that reduces inconvenience to patients whilst increasing the response rate to pegylated interferon alfa-2b in combination with ribavirin.		
FND recommendation:	**Not included in the Paediatric Formulary pending further consultation.** **No change required for GGC Adult Formulary.**		✘
ADTC Decision 13/08/12	**AGREED**		

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

Medicine name:	**Dasatinib, Nilotinib, Imatinib**	Reason for consideration:	**NICE MTA**
Indication under review:	**Chronic myeloid leukaemia (CML) - 2nd line treatment**		
SMC/ HIS reference:	**NICE MTA 241 (partial update of previous guidance to review Imatinib resistance/intolerance)**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	Nilotinib is recommended for the treatment of chronic or accelerated phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML) in adults whose CML is resistant to treatment with standard-dose imatinib **or** who have imatinib intolerance **and** if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme. Dasatinib is not recommended for the treatment of chronic, accelerated or blast-crisis phase CML in adults with imatinib intolerance or whose CML is resistant to treatment with standard-dose imatinib. High-dose imatinib is not recommended for the treatment of chronic, accelerated or blast-crisis phase Philadelphia-chromosome-positive CML that is resistant to standard-dose imatinib. People who are currently receiving dasatinib or high-dose imatinib for the treatment of CML should have the option to continue treatment until they and their clinicians consider it appropriate to stop.		
FND recommendation and Formulary restriction:	**Guidance noted.** **Dasatinib to be removed from the Adult Formulary (previously accepted by SMC, May 2007).** **No other changes to Formulary status required**		✘
ADTC Decision 13/08/12	**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:	**Dasatinib, Nilotinib, Imatinib**	Reason for consideration:	**NICE MTA**
Indication under review:	**Chronic myeloid leukaemia (CML) – 1st line treatment**		
SMC/ HIS reference:	**NICE MTA 251 (part review of technology appraisal guidance 70)**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	Standard-dose imatinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive chronic myeloid leukaemia (CML). Nilotinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme. Dasatinib is not recommended for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML. People currently receiving dasatinib that is not recommended above should be able to continue treatment until they and their clinician consider it appropriate to stop		
FND recommendation and Formulary restriction:	**Guidance noted. No changes to Formulary status required.**		✘
ADTC Decision 13/08/12	**AGREED**		

Medicine name:	**Lapatinib and Trastuzumab**	Reason for consideration:	**NICE MTA**
Indication under review:	**1st line treatment of metastatic hormone receptor positive breast cancer that overexpresses HER2 in combination with an aromatase inhibitor.**		
SMC/ HIS reference:	**NICE MTA 257**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	➢ Lapatinib in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic ormonereceptor-positive breast cancer that overexpresses human epidermal growth factor receptor 2 (HER2). ➢ Trastuzumab in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormonereceptor-positive breast cancer that overexpresses HER2. ➢ Postmenopausal women currently receiving lapatinib or trastuzumab in combination with an aromatase inhibitor that is not recommended according to 1.1 or 1.2 should have the option to continue treatment until they and their clinicians consider it appropriate to stop.		
FND recommendation and Formulary restriction:	**Guidance noted. No changes to Formulary status required.**		✘
ADTC Decision 13/08/12	**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:	**Methotrexate pre-filled syringes (Metoject®)** *Medac UK*	Reason for consideration:	**New business case**
Indication under review:	**Treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs (DMARD) is indicated.**		
SMC/ HIS reference:	**SMC 332/06 [Abbreviated Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	For patients in whom parenteral methotrexate is appropriate, this is the first licensed parenteral formulation for this indication. This is on the GGC Formulary for specialist use only. A business case outlining that GPs are reimbursed monitoring costs.		
FND recommendation:	**N/A**		
ADTC Decision 13/08/12	**AGREED that this be amended in the GGC Total Formulary to specialist initiation.**		

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