NEW DRUG RECOMMENDATIONS
SEPTEMBER 2012

NHS Greater Glasgow and Clyde

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

Medicine name:	**Velaglucerase (Vpriv®)** *Shire Pharmaceuticals Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Long-term enzyme replacement therapy in patients with type 1 Gaucher disease.**		
SMC/ HIS reference:	**SMC 681/11 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Velaglucerase alfa has been shown to be non-inferior to another enzyme replacement treatment in patients with type 1 Gaucher disease. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of velaglucerase. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.		
FND recommendation:	**Ⓢ Included on Total Formulary for the indication in question restricted to supervision by a physician experienced in the management of patients with Gaucher disease.**		✓R
ADTC Decision 08/10/12	**AGREED**		

Medicine name:	**Collagenase clostridium histolyticum (Xiapex®)** *Pfizer Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of Dupuytren's contracture in adult patients with a palpable cord.**		
SMC/ HIS reference:	**SMC 715/11 [Resubmission] [Deferred Decision]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: restricted to use as an alternative to limited fasciectomy in adult patients with Dupuytren's contracture of moderate severity (as defined by the British Society for Surgery of the Hand (BSSH), with a palpable cord and up to two affected joints per hand, who are suitable for limited fasciectomy, but for whom percutaneous needle fasciotomy is not considered a suitable treatment option. Collagenase clostridium histolyticum compared to placebo significantly reduces primary joint contracture in adults with Dupuytren's contracture and palpable cord. The cost-effectiveness of collagenase clostridium histolyticum relative to percutaneous needle fasciotomy was not demonstrated.		
FND recommendation:	**Ⓢ Included on Total Formulary for the indication in question restricted to use in accordance with local protocol.**		✓R
ADTC Decision 08/10/12	**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:	**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 [Resubmission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: restricted to use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. Fingolimod reduced the annualised relapse rate significantly more than a beta-interferon in patients with clinically active RRMS. An indirect comparison also demonstrated similar efficacy to another disease modifying therapy in established use in RRMS. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fingolimod. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.		
FND recommendation:	**Ⓢ Included on Total Formulary for the indication in question restricted to use in highly active RRMS only in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.**		✓R
ADTC Decision 08/10/12	**AGREED**		

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] [Deferred Decision]**		
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:	**Ⓢ Included in the Total Formulary for the indication in question.** **It is restricted to use in patients who have received only one prior chemotherapy regimen and is to be used in accordance with regional protocol**		✓R
ADTC Decision 08/10/12	**AGREED**		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
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Ⓢ Specialist use only

Medicine name:	**Everolimus (Afinitor®)** *Novartis Pharmaceuticals UK Limited*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of unresectable or metastatic, well or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease.**		
SMC/ HIS reference:	**SMC 777/12 [Full Submission] [Deferred Decision]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Everolimus was superior to placebo in prolonging progression-free survival in adults with progressive, advanced pNET who were receiving best supportive care.		
FND recommendation:	**Included in the Total Formulary for the indication in question.** **It is restricted to use in accordance with regional protocol**		✓R
ADTC Decision 08/10/12	**AGREED**		

Medicine name:	**Colecalciferol (Fultium-D$_3$®)** *Internis Pharmaceuticals Limited*	Reason for consideration:	**New medicine**
Indication under review:	**In adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.**		
SMC/ HIS reference:	**SMC 801/12 [Full Submission]**		
Summary of advice:	**Accepted for use within NHS Scotland**		
SMC/HIS restriction and comments:	The therapeutic use and safety profile of colecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. There are no comparative data for Fultium-D$_3$® as it is the first licensed oral vitamin D monotherapy formulation.		
FND recommendation:	**Included on the Total Formulary for the indication in question.** Recommended that a PostScript article on the place in therapy of this medicine is considered to support introduction.		✓
ADTC Decision 08/10/12	**AGREED**		

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

Medicine name:	**Fluticasone proprionate and formoterol fumarate inhaler (Flutiform®)** *Napp Pharmaceuticals Ltd*	Reason for consideration:	**New combination**
Indication under review:	**In the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β$_2$ agonist (LABA)] is appropriate:** • **for patients not adequately controlled on ICS and 'as required' inhaled short-acting β$_2$ agonist or** • **for patients already adequately controlled on both an ICS and a LABA.**		
SMC/ HIS reference:	**SMC 736/11 [Full Submission]**		
Summary of advice:	**Accepted for use in NHS Scotland**		
SMC/HIS restriction and comments:	Flutiform® should be used in patients for whom fluticasone and formoterol are appropriate choices of corticosteroid and long-acting beta-agonist, respectively, and for whom a metered dose inhaler is an appropriate delivery device. It has demonstrated clinical non-inferiority to another combination product containing a corticosteroid and long-acting beta$_2$-agonist and may offer cost savings.		
FND recommendation:	**Included on Preferred List for the indication in question restricted for use in patients on step 3 or above of the BTS/SIGN asthma guidelines**		✓R
ADTC Decision 08/10/12	**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:	**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 [Resubmission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: restricted for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005). In a randomised, double-blind, controlled study conducted in patients who were intolerant to methotrexate, or for whom methotrexate was inappropriate, tocilizumab monotherapy was superior to a TNF antagonist for several clinically relevant outcomes (DAS28 scores, DAS28 remission, ACR response rates). This SMC advice takes account of the benefits of a Patient Access Scheme that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the availability of the Patient Access Scheme in NHS Scotland.		
FND recommendation:	**Included on Total Formulary for the indication in question restricted to use in accordance with the British Society for Rheumatology (BSR) guidelines (2005).**		✓R
ADTC Decision 08/10/12	**AGREED**		

Medicine name:	**Ivabradine (Procoralan®)** *Servier Laboratories Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 beats per minute (bpm), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated.**		
SMC/ HIS reference:	**SMC 805/12 [Full Submission]**		
Summary of advice:	**Accepted for restricted use in NHS Scotland**		
SMC/HIS restriction and comments:	SMC restriction: for initiation only in patients whose resting heart rate remains ≥75 beats per minute despite optimal standard therapy. In a post-hoc subgroup analysis of the pivotal study in patients meeting the licensed indication, ivabradine was significantly more effective than placebo at reducing the risk of a composite of cardiovascular death or hospitalisation for worsening heart failure. However, in patients on the target dose of beta-blocker, ivabradine was not significantly more effective.		
FND recommendation:	**Included on Total Formulary for the indication in question restricted to patients whose resting heart rate remains ≥75 beats per minute despite optimal standard therapy. It should be initiated by prescribers working within specialist heart failure teams**		✓R
ADTC Decision 08/10/12	**AGREED**		

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

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:	**Tegafur / gimeracil / oteracil hard capsules (Teysuno®)** *Nordic Pharma Ltd*	Reason for consideration:	**New medicine (combination)**
Indication under review:	**Indication in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.**		
SMC/ HIS reference:	**SMC 802/12 [Full Submission]**		
Summary of advice:	**Accepted for 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:	**Not included in the GGC Adult Formulary for the indication in question pending protocol. (Regional Cancer Advisory Group).**		✘
ADTC Decision 08/10/12	**AGREED**		

Section 5: Medicines not recommended by SMC

Medicine name:	**Tocofersolan (Vedrop®)** *Orphan Europe UK*	Reason for consideration:	**New medicine**
Indication under review:	**Vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region.**		
SMC/ HIS reference:	**SMC 696/11 [Resubmission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	In an open-label, single-arm study, 96% of patients had an improved or stable neurological score after 2.5 years of treatment with tocofersolan. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.		
FND recommendation:	**Not included in the GGC Paediatric Formulary.**		✘

Medicine name:	**Vemurafenib (Zelboraf®)** *Roche Products Ltd*	Reason for consideration:	**New medicine**
Indication under review:	**As monotherapy for the treatment of adults patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.**		
SMC/ HIS reference:	**SMC 792/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	A phase III, open-label study has demonstrated a significant improvement for the co-primary endpoints of overall survival and progression free survival for vemurafenib relative to an intravenous single agent chemotherapy regimen, in patients with previously untreated unresectable stage IIIC or stage IV melanoma with V600E BRAF mutation. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.		
FND recommendation:	**Not included in the GGC Adult Formulary.**		✘

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
S Specialist initiation only
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Medicine name:	**Bevacizumab (Avastin®)** *Roche Products Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Bevacizumab in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.**		
SMC/ HIS reference:	**SMC 806/12 [Full Submission]**		
Summary of advice:	**Not recommended for use in NHS Scotland**		
SMC/HIS restriction and comments:	In two phase III studies, bevacizumab in combination with carboplatin and paclitaxel significantly increased progression free survival compared with carboplatin and paclitaxel alone in patients with advanced ovarian cancer. The submitting company's base case economic analysis was based on an unlicensed dose of the medicine and this is not within the SMC remit. For the sensitivity analysis using the licensed dose, 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:	**Caffeine citrate (Peyona®)** *Chiesi Farmaceutica SpA*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of primary apnoea of premature newborns.**		
SMC/ HIS reference:	**SMC 814/12 [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 added to the GGC Paediatric Formulary for the indication in question.**		✘

Medicine name:	**Pasireotide (Sifnifor®) solution for injection** *Novartis Pharmaceuticals Limited*	Reason for consideration:	**New medicine**
Indication under review:	**Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed.**		
SMC/ HIS reference:	**SMC 815/12 [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 added to the GGC Adult Formulary for the indication in question**		✘

Medicine name:	**Strontium ranelate (Protelos®)** *Servier Laboratories Limited*	Reason for consideration:	**New indication**
Indication under review:	**Treatment of osteoporosis in men at increased risk of fracture.**		
SMC/ HIS reference:	**SMC 816/12 [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 added to 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:	**Zonisamide (Zonegran®)** *Eisai Ltd*	Reason for consideration:	**New indication**
Indication under review:	**Monotherapy for the treatment of partial seizures (with or without secondary generalisation) in adults with newly diagnosed epilepsy.**		
SMC/ HIS reference:	**SMC 817/12 [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 added to the GGC Adult Formulary for the indication in question.**		✘

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

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

Medicine name:	**Oral Typhoid Vaccine (Vivotif®)** *Galen Ltd*	Indication:	**Active immunisation against typhoid fever.**
Reason for consideration:	**Formulary Appeal**	SMC decision:	**Not applicable**
FND recommendation, restrictions on use and comments: **Appeal not upheld. Insufficient evidence of benefit over existing formulary options.**			✓R
ADTC Decision 08/10/12	**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