NEW DRUG RECOMMENDATIONS
JUNE 2013

NHS Greater Glasgow and Clyde

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

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 [Deferred decision]		
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:	Ⓢ Included in the GGC Total Formulary for the indication in question restricted to specialist use in accordance with NHSGGC protocol		✓R
ADTC Decision 10/06/13	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] [Deferred decision]		
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:	Ⓢ Included in the Total Formulary for the indication in question pending protocol.		✓R
ADTC Decision 10/06/13	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:	Linaclotide hard capsules (Constella®) *Almirall SA*	Reason for consideration:	New medicine
Indication under review:	Symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.		
SMC/ HIS reference:	SMC 869/13 [Full Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: linaclotide is restricted for use in patients with moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options. In two pivotal phase III studies linaclotide was superior to placebo for the co-primary endpoints of abdominal pain/discomfort responders and IBS degree-of-relief responders at 12 weeks. There are no comparative efficacy data versus first- or second-line treatments.		
FND recommendation:	Included in the GGC Total Formulary for the indication in question. Restricted to use in adult patients with moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options. A treatment guideline should be developed to inform place in practice. Consideration to be given by ADTC regarding whether use is further restricted to specialist initiation. Prescribing notes: ▪ Other suitable treatment options may include laxatives, antispasmodics and off-label use of antidepressants. ▪ Patients should be reviewed following 4 weeks of treatment and the medicine discontinued if they have not shown an appropriate response.		✓R
ADTC Decision 10/06/13	Included in the GGC Total Formulary for the indication in question pending protocol plus restriction above. ADTC considered this medicine did not require to be reserved for specialist initiation		

Medicine name:	Mirabegron prolonged–release tablets (Betmiga®) *Astellas Pharma Ltd*	Reason for consideration:	New medicine
Indication under review:	For symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.		
SMC/ HIS reference:	SMC 862/13 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Mirabegron was associated with modest treatment benefits over placebo in reducing symptoms associated with overactive bladder syndrome, including frequency and incontinence. Alternative treatments are available at a lower drug acquisition cost.		
FND recommendation:	Included in the GGC Total Formulary for the indication in question.		✓
ADTC Decision 10/06/13	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:	Ranibizumab (Lucentis®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	For the treatment of visual impairment due to macular oedema (MO) secondary to retinal vein occlusion (RVO) (branch RVO or central RVO) in adults. This submission relates to branch RVO only.		
SMC/ HIS reference:	SMC 732/11 [Resubmission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	Ranibizumab was associated with significant improvements in visual acuity during 6-month sham-controlled treatment in a phase III randomised double-blind study in patients with branch retinal vein occlusion. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ranibizumab. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. SMC has previously accepted ranibizumab for use in macular oedema secondary to central retinal vein occlusion (CRVO). This advice now extends its use to patients with branch retinal vein occlusion (BRVO).		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question pending protocol. (Previously accepted for CRVO with same SMC Reference No).		✓R
ADTC Decision 10/06/13	AGREED		

Medicine name:	Saxagliptin plus metformin tablets (Komboglyze®) *Bristol Myers Squibb/Astra Zeneca*	Reason for consideration:	New combination
Indication under review:	Adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets.		
SMC/ HIS reference:	SMC 870/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: Use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate. Saxagliptin represents an alternative to other agents such as thiazolidinediones. Efficacy, as assessed by measurement of HbA1c, is comparable to another dipeptidyl peptidase-4 inhibitor. It appears to have minimal effect on body weight. Saxagliptin/metformin is also licensed for use in combination with insulin for the treatment of type 2 diabetes. The manufacturer's submission related only to the use of saxagliptin and metformin in combination therefore SMC cannot recommend the use of saxagliptin/metformin in combination with insulin.		
FND recommendation:	Included in the GGC Total Formulary for the indication in question. Restricted to use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate. Combination preparations are further restricted to use only in those patients who have demonstrable compliance issues with the separate constituents.		✓R
ADTC Decision 10/06/13	AGREED		

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

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

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 5: Medicines not recommended by SMC

Medicine name:	Abiraterone (Zytiga®) *Janssen-Cilag Ltd*	Reason for consideration:	New indication
Indication under review:	Zytiga is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.		
SMC/ HIS reference:	SMC 873/13 [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. The sponsor company plan to make a submission to SMC in December 2013.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Medicine name:	Canakinumab (Ilaris®) *Novartis Pharmaceuticals Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 2 years and older with body weight of 7.5 kg or above including: ▪ Muckle-Wells Syndrome (MWS) ▪ Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA). Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.		
SMC/ HIS reference:	SMC 882/13 [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 or Paediatric Formulary for the indication in question.		✘

Medicine name:	Canakinumab (Ilaris®) *Novartis Pharmaceuticals Ltd*	Reason for consideration:	New medicine
Indication under review:	Symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.		
SMC/ HIS reference:	SMC 883/13 [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:	Crizotinib, hard capsule (Xalkori®) *Pfizer Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).		
SMC/ HIS reference:	SMC 865/13 [Full Submission]		
Summary of advice:	Not recommended for use in NHS Scotland		
SMC/HIS restriction and comments:	In a phase III clinical study in patients with previously treated anaplastic lymphoma kinase (ALK)-positive advanced NSCLC, crizotinib significantly increased progression-free survival compared with standard chemotherapy. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC, 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:	Everolimus (Votubia®) *Novartis Pharmaceuticals Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of adult patients with renal angiomyolipoma associated with tuberous sclerosis complex (TSC) who are at risk of complications (based on factors such as tumour size or presence of aneurysm, or presence of multiple or bilateral tumours) but who do not require immediate surgery.		
SMC/ HIS reference:	SMC 884/13 [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:	Fluocinolone acetonide (Iluvien®) *Alimera Sciences Limited*	Reason for consideration:	New medicine
Indication under review:	Treatment of vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies.		
SMC/ HIS reference:	SMC 864/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	The safety and efficacy of fluocinolone intravitreal implant was assessed in two randomised, double-masked, controlled phase III studies in patients with diabetic macular oedema. Significantly more patients treated with fluocinolone had a clinically significant improvement in visual acuity at two and three years versus sham injection. Subgroup analysis supported this finding in patients with chronic diabetic macular oedema (median duration at least 3 years). Fluocinolone was associated with an increased risk of complications: accelerated cataract formation requiring corrective surgery, and raised intraocular pressure. 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.		✘

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:	Ivacaftor tablets (Kalydeco®) *Vertex Pharmaceuticals UK Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.		
SMC/ HIS reference:	SMC 827/12 [Resubmission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	Ivacaftor has demonstrated superiority over placebo measured by absolute change in forced expiratory volume in one second (FEV1) % predicted in two phase III, double-blind randomised studies. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC 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 or Paediatric Formulary for the indication in question. Eligible patients will receive this medicine through arrangements described within the Scottish Government's Rare Conditions Medicines Fund.		✘

Medicine name:	Rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®) *Genus Pharmaceuticals*	Reason for consideration:	New combination
Indication under review:	Initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines.		
SMC/ HIS reference:	SMC 876/13 [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:	Tafamidis meglumine (Vyndaqel®) soft capsules *Pfizer Limited*	Reason for consideration:	New medicine
Indication under review:	Treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment.		
SMC/ HIS reference:	SMC 877/13 [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 these indications. 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:	Vildagliptin (Galvus®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of type 2 diabetes mellitus in adults: ▪ as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control; ▪ in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.		
SMC/ HIS reference:	SMC 875/13 [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 these indications. 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

Medicine name:	Vildagliptin/metformin hydrochloride film-coated tablets (Eucreas®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New formulation
Indication under review:	Treatment of type 2 diabetes mellitus: ▪ in combination with a sulphonylurea (ie triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulphonylurea ▪ in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.		
SMC/ HIS reference:	SMC 874/13 [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 these indications. 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:	Lisdexamfetamine dimesylate capsules (Elvanse®) *Shire Pharmaceuticals Contracts Ltd*	Reason for consideration:	New medicine
Indication under review:	As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate.		
SMC/ HIS reference:	SMC 863/13 [Full Submission]		
Summary of advice:	Accepted for use in NHS Scotland		
SMC/HIS restriction and comments:	In a multi-centre, randomised, double-blind, controlled study in children and adolescents with ADHD, treatment with lisdexamfetamine was associated with a shorter time to first response compared with a non-stimulant, centrally-acting sympathomimetic agent. A greater proportion of lisdexamfetamine treated patients achieved improvements in symptom scores and functioning than those treated with the active comparator.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question restricted to specialist initiation.		✓R
ADTC Decision 10/06/13	AGREED		

Medicine name:	Pegylated interferon alfa-2a (Pegasys®) *Roche Products Limited*	Reason for consideration:	New indication
Indication under review:	In combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA). When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case-by-case basis.		
SMC/ HIS reference:	SMC 871/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use in NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology. Results from phase III studies in paediatric patients suggest that efficacy and safety in this patient group is broadly similar to that in adults, with the exception of the reported effects on growth in children. The Scottish Medicines Consortium has previously accepted this product for restricted use in adults. Pegylated interferon alpha-2a is listed in the British National Formulary for Children 2012-2013 for the treatment of chronic hepatitis C.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use in paediatric infectious disease or paediatric gastroenterology.		✓R
ADTC Decision 10/06/13	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 7: Other Formulary decisions – Appeals, reviews, NICE/SIGN guidance

Medicine name:	Colistimethate dry powder inhalation (Colobreathe®) *Forrest Labs* Tobramycin inhalation powder (TOBI Podhaler) *Novartis Pharmaceuticals UK*	Indication:	*Pseudomonas* infection in cystic fibrosis
Reason for consideration:	NICE Multiple Technology Appraisal	SMC decision:	NICE TA276 SMC 783/12 Accepted for use in NHS Scotland

FND recommendation, restrictions on use and comments:

The guidance from NICE is noted and the following changes are to be made to the GGC Formulary

- Colistimethate dry powder inhalation (Colobreathe®) is included in the Total Formulary, restricted to use where nebulised colistimethate is not tolerated and tobramycin is being considered.

  Formulary advice unchanged for TOBI Podhaler

- Tobramycin dry powder for inhalation (DPI) is recommended as an option for treating chronic pulmonary infection caused by *Pseudomonas aeruginosa* in people with cystic fibrosis only if:
  - nebulised tobramycin is considered an appropriate treatment, that is, when colistimethate sodium is contraindicated, is not tolerated or has not produced an adequate clinical response and
  - the manufacturer provides tobramycin DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS.
- Colistimethate sodium DPI is recommended as an option for treating chronic pulmonary infection caused by *P. aeruginosa* in people with cystic fibrosis only if:
  - they would clinically benefit from continued colistimethate sodium but do not tolerate it in its nebulised form and thus tobramycin therapy would otherwise be considered and
  - the manufacturer provides colistimethate sodium DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS.
- People currently using tobramycin DPI or colistimethate sodium DPI that is not recommended according to 1.1 or 1.2 should be able to continue treatment until they and their clinician consider it appropriate to stop. For children and young people this decision should be made jointly by the clinician, the child or young person and their parents or carers.

✓R

ADTC Decision 10/06/13	AGREED

Medicine name:	Omalizumab (Xolair®) *Novartis*	Indication:	Severe persistent allergic asthma
Reason for consideration:	NICE Multiple Technology Appraisal	SMC decision:	TA278

FND recommendation, restrictions on use and comments:

- The guidance from NICE is noted. No changes required to the GGC Adult Formulary.
- Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older:
  - who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), and
  - only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme.
- Optimised standard therapy is defined as a full trial of and, if tolerated, documented compliance with inhaled high-dose corticosteroids, long-acting beta$_2$ agonists, leukotriene receptor antagonists, theophyllines, oral corticosteroids, and smoking cessation if clinically appropriate.
- People currently receiving omalizumab whose disease does not meet the criteria in 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop

✓R

ADTC Decision 10/06/13	AGREED

Medicine name:	Tiotropium solution for inhalation (Spiriva Respimat®) *Boehringer Ingelheim*	Indication:	Maintenance treatment of chronic obstructive pulmonary disease (COPD)
Reason for consideration:	Formulary Appeal	SMC decision:	SMC 411/07 [Abbreviated] Accepted for restricted use in NHS Scotland
FND recommendation, restrictions on use and comments: Tiotropium solution for inhalation (as the Spiriva Respimat® device) is to be removed from the GGC Adult Formulary due to safety concerns. The dry powder inhaler device (Spiriva Handihaler®) continues to be included.			✘
ADTC Decision 10/06/13	AGREED		

Medicine name:	Beclomethasone/Formoterol for inhalation (Fostair®) *Chiesi*	Indication:	Maintenance and reliever therapy for asthma
Reason for consideration:	Formulary Housekeeping	SMC decision:	SMC 373/07
FND recommendation, restrictions on use and comments: Updated prescribing note: - In selected adult patients with asthma at step 3 who are poorly controlled or in selected adult patients at step 2 (above beclometasone 400micrograms/day or equivalent and poorly controlled), the use of beclomethasone and formoterol in a single inhaler as rescue medication instead of a short-acting beta$_2$ agonist, in addition to its regular use as controller therapy, has been shown to be an effective treatment regime.			✓R
ADTC Decision 10/06/13	AGREED		

Medicine name:	Cinacalcet (Mimpara®) *Amgen*	Indication:	Secondary hyperparathyroidism in end stage renal disease
Reason for consideration:	Formulary Housekeeping	SMC decision:	NICE TA117
FND recommendation, restrictions on use and comments: Change in restriction from specialist use only to specialist initiation to reflect current practice. Additional prescribing note: All monitoring and review related to this medicine is to be carried out at specialist renal clinics.			✓R
ADTC Decision 10/06/13	AGREED		

Medicine name:	Piroxicam gel (Feldene®) *Pfizer*	Indication:	Topical non-steroidal anti inflammatory drug
Reason for consideration:	Formulary Housekeeping	SMC decision:	Not applicable
FND recommendation, restrictions on use and comments: Moved from Total Formulary to Preferred List, replacing Movelat® which will be Total Formulary			✓R
ADTC Decision 10/06/13	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:	Betnovate C® (betamethasone and clioquinol)	Indication:	Topical corticosteroid (Antimicrobial)
Reason for consideration:	Formulary Housekeeping	SMC decision:	Not applicable

FND recommendation, restrictions on use and comments: This product has been discontinued but a non-proprietary alternative is available at considerably increased cost. Moved from the Preferred List to the Total Formulary in the interim but dermatologists have been contacted to ascertain if this can be completely removed from the Formulary. Fucibet moved from Total Formulary to the Preferred List	✓R
ADTC Decision 10/06/13	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