# NEW DRUG RECOMMENDATIONS
# JANUARY 2013

NHS Greater Glasgow and Clyde

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

| | | | |
|---|---|---|---|
| Medicine name: | **Apixaban tablets (Eliquis®)**<br>*Bristol-Myers Squibb / Pfizer* | Reason for consideration: | **New indication** |
| Indication under review: | **The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥II).** | | |
| SMC/ HIS reference: | **SMC 836/13 [Full Submission]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | Apixaban was superior to standard oral anticoagulation at preventing stroke or systemic embolism in one large, double-blind study in patients with atrial fibrillation and at least one risk factor for stroke. It was also associated with a significant reduction in risk of major bleeding. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question 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.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED – commitment to review the restriction in light of anticipated local/national advice.** | | |

| | | | |
|---|---|---|---|
| Medicine name: | **Ceftaroline fosamil infusion (Zinforo®)**<br>*AstraZeneca UK Ltd* | Reason for consideration: | **New medicine** |
| Indication under review: | **Treatment of complicated skin and soft tissue infections in adults.** | | |
| SMC/ HIS reference: | **SMC 830/12 [Full Submission]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: As indicated below in FND recommendation<br><br>In two randomised, controlled clinical studies, intravenous ceftaroline fosamil was non-inferior to intravenous vancomycin plus aztreonam in adult patients with complicated skin and skin structure infections.<br><br>Ceftaroline is also licensed for the treatment of community acquired pneumonia. As the company submission related only to the treatment of skin and soft tissue infections, SMC cannot recommend the use of ceftaroline in community acquired pneumonia. | | |
| FND recommendation: | **Ⓢ Included in the GGC Total Formulary for the indication in question restricted to specialist use on the advice of local microbiologists or specialists in infectious disease for patients with known or suspected meticillin resistant *Staphylococcus aureus* (MRSA) infection in the following settings:**<br>– **For Gram-positive only infections where vancomycin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv or linezolid iv is normally used.**<br>– **For polymicrobial Gram-positive and common Gram-negative pathogens*, where vancomycin iv in combination with gentamicin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv in combination with gentamicin iv, or linezolid iv in combination with gentamicin iv, or tigecycline iv is normally used.** | | ✓R |
| ADTC Decision 18/02/13 | **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: | **Dapagliflozin tablets (Forxiga®)**<br>*Bristol-Myers Squibb / AstraZeneca* | Reason for consideration: | **New medicine** |
|---|---|---|---|
| Indication under review: | **For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.** | | |
| SMC/ HIS reference: | **SMC 799/12 [Full Submission – Deferred Advice]** | | |
| Summary of advice: | **Accepted for restricted use within NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: Dapagliflozin is restricted to use as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate.<br><br>In three phase III randomised, controlled studies, dapagliflozin when added to metformin was non-inferior to a sulphonylurea in combination with metformin, and superior to placebo in terms of glycaemic control, as measured by change in HbA1c. This was accompanied by reductions in body weight and the risk of hypoglycaemia with dapagliflozin treatment was similar to placebo and lower, when compared with sulphonylurea.<br><br>In a phase III randomised, controlled study, dapagliflozin treatment, when added to an insulin-containing regimen, was associated with; greater reductions in HbA1c, in body weight; and similar rates of hypoglycaemia when compared with placebo.<br><br>The submitting companies did not present a sufficiently robust economic analysis to gain acceptance by SMC for use in addition to insulin in patients who have inadequate glycaemic control.<br><br>Dapagliflozin is also licensed for use as monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. The manufacturers' submission related only to the use of dapagliflozin when used as dual therapy in combination with either metformin or insulin. SMC cannot recommend the use of dapagliflozin as monotherapy. | | |
| FND recommendation: | Ⓢ **Included in the GGC Total Formulary for the indication in question restricted to specialist initiation as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulphonylurea is inappropriate.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED subject to the words "specialist initiation" being replaced with "initiation by clinicians experienced in the treatment of diabetes".** | | |

| Medicine name: | **Dexamethasone (Ozurdex®)**<br>*Allergan Ltd* | Reason for consideration: | **New formulation** |
|---|---|---|---|
| Indication under review: | **Treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion.** | | |
| SMC/ HIS reference: | **SMC 652/10 [Resubmission] [Deferred decision]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: for use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment.<br><br>In two phase III studies dexamethasone 700 microgram intravitreal implant was superior to sham administration at day 90 for the proportion of patients with a best corrected visual acuity improvement of ≥15 letters. Longer-term effectiveness of treatment is uncertain. | | |
| FND recommendation: | Ⓢ **Included in the GGC Total Formulary for the indication in question restricted to specialist use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment in accordance with local protocol.** | | ✓R |
| ADTC Decision 18/02/13 | **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: | **Ferumoxytol injection (Rienso®)**<br>*Takeda UK Ltd* | Reason for consideration: | **New medicine** |
|---|---|---|---|
| Indication under review: | **Intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease.** | | |
| SMC/ HIS reference: | **SMC 833/13 [Full Submission]** | | |
| Summary of advice: | **Accepted for restricted use within NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used.<br><br>In two phase III studies the mean increase from baseline in haemoglobin was significantly higher for ferumoxytol than oral iron in non-haemodialysis dependent patients with chronic kidney disease. A mixed treatment comparison demonstrated equivalent efficacy outcomes for ferumoxytol versus a range of intravenous iron preparations. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question restricted to specialist use for the treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used and when standard IV iron is inappropriate due to its administration schedule**. | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| Medicine name: | **Glycopyrronium for inhalation (Seebri Breezhaler®)**<br>*Novartis Pharmaceuticals Ltd* | Reason for consideration: | **New formulation** |
|---|---|---|---|
| Indication under review: | **As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).** | | |
| SMC/ HIS reference: | **SMC 829/12 [Full Submission]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | In two phase III studies, glycopyrronium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [$FEV_1$]) after 12 weeks. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question.** | | ✓ |
| ADTC Decision 18/02/13 | **AGREED** | | |

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

| Medicine name: | **Budesonide gastro-resistant capsule (Budenofalk®)**<br>*Dr Falk Pharma* | Reason for consideration: | **New indication** |
|---|---|---|---|
| Indication under review: | **Symptomatic relief of chronic diarrhoea due to collagenous colitis.** | | |
| SMC/ HIS reference: | **SMC 828/12 [Full submission]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | Budesonide (Budenofalk®) provides symptomatic improvement of diarrhoea associated with collagenous colitis compared with placebo. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question restricted to specialist initiation.** | | ✓R |
| ADTC Decision 18/02/13 | **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: | **Budesonide gastro-resistant granules (Budenofalk®)**<br>*Dr Falk Pharma* | Reason for consideration: | **New formulation** |
|---|---|---|---|
| Indication under review: | **Induction of remission in patients with active collagenous colitis.** | | |
| SMC/ HIS reference: | **SMC 831/12 [Abbreviated submission]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | Budesonide gastro-resistant granules provides a once daily alternative to budesonide gastro-resistant 3mg capsules (which are given three times daily) at no additional cost. The granules may have advantages for patients who have difficulty swallowing. | | |
| FND recommendation: | Ⓢ **Included in the GGC Total Formulary for the indication in question restricted to specialist initiation.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| Medicine name: | **Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®)**<br>*Ipsen Ltd* | Reason for consideration: | **New indication** |
|---|---|---|---|
| Indication under review: | **Focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy.** | | |
| SMC/ HIS reference: | **SMC 353/07 [Resubmission]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: for focal spasticity of the upper limbs associated with stroke.<br><br>Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) produces a localised reduction in muscle tone in patients with post-stroke upper limb spasticity and can improve patient disability at 16 weeks. It continues to be effective after repeated administrations with no new adverse events apparent. | | |
| FND recommendation: | Ⓢ **Included in the GGC Total Formulary for the indication in question restricted to specialist use for focal spasticity of the upper limbs associated with stroke.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| Medicine name: | **Colecalciferol 800 units (20 micrograms vitamin $D_3$) tablets (Desunin 800 IU®)**<br>*Meda* | Reason for consideration: | **New formulation** |
|---|---|---|---|
| Indication under review: | **Prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered.** | | |
| SMC/ HIS reference: | **SMC 840/13 [Abbreviated Submission]** | | |
| Summary of advice: | **Accepted for use in 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 colecalciferol (Desunin®). It is the same cost as another vitamin D preparation. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question.**<br><br>**Desunin® contains 800 units of colecalciferol. It should be noted that this preparation is double the daily recommended dose of Vitamin D for adults who are considered to be at risk of vitamin D deficiency as outlined in guidance issued from the Chief Medical Officer for Scotland in February 2012. Healthy Start vitamins contain 400 units of vitamin D and are available for eligible patient groups in NHSGGC and vitamin supplement preparations containing 400 units of vitamin D are readily available for purchase over the counter from pharmacies and health food shops.**<br><br>**Guidance on when to measure vitamin D levels and the subsequent management are currently in development by the GG&C Osteoporosis Group and Biochemistry Department.** | | ✓ |
| ADTC Decision 18/02/13 | **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: | **Etanercept injection (Enbrel®)**<br>*Pfizer Ltd* | Reason for consideration: | **Product update** |
|---|---|---|---|
| Indication under review: | **For the treatment of**<br>– **polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate;**<br>– **psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate;**<br>– **enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.** | | |
| SMC/ HIS reference: | **SMC 842/13 [Abbreviated Submission]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology).<br><br>Etanercept has previously been accepted by the SMC for the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.<br><br>Etanercept is listed in the British National Formulary for Children 2011-2012 as one of a number of treatment options for juvenile idiopathic arthritis including the above subtypes. | | |
| FND recommendation: | **Included in the GGC Total Formulary and GGC Paediatric Formulary for the indications in question restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology).** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| Medicine name: | **Etanercept injection (Enbrel®)**<br>*Pfizer Ltd* | Reason for consideration: | **New indication** |
|---|---|---|---|
| Indication under review: | **For the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.** | | |
| SMC/ HIS reference: | **SMC 781/12 [Abbreviated Submission] [Deferred decision]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction:<br>- The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10;<br>- the psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments;<br>- etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks.<br><br>Etanercept has previously been accepted for use in this indication in adults in NHS Scotland as NHS Health Improvement Scotland advised that NICE Multiple Technology Appraisal No 103 is valid for Scotland. Etanercept has previously been accepted for restricted use by SMC in adolescents and children from the age of 8 years.<br><br>Etanercept is also listed in the British National Formulary for Children 2011-2012 as one of a number of drugs affecting the immune response available for treatment of severe refractory psoriasis. | | |
| FND recommendation: | **Included in the GGC Paediatric Formulary for the indication in question restricted to specialist use in patients where:**<br>– **The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10;**<br>– **the psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments;**<br>– **etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks** | | ✓R |
| ADTC Decision 18/12/13 | **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: | **Linagliptin tablets (Trajenta®)**<br>*Boehringer Ingelheim and Eli Lilly* | Reason for consideration: | **New indication** |
|---|---|---|---|
| Indication under review: | **The treatment of type 2 diabetes mellitus to improve glycaemic control in adults:**<br>**as monotherapy:**<br>– **in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment.**<br>**as combination therapy:**<br>– **in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products does not provide adequate glycaemic control.**<br>– **in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.** | | |
| SMC/ HIS reference: | **SMC 850/13 [Full Submission]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction:<br>– as monotherapy in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.<br>– as combination therapy with a sulphonylurea and metformin when diet and exercise plus dual therapy does not provide adequate glycaemic control.<br><br>SMC is unable to recommend the use of linagliptin in combination with insulin as the economic case has not been demonstrated.<br><br>Treatment with linagliptin reduces HbA1c levels significantly more than placebo when used as monotherapy or in combination with metformin and a sulphonylurea or in combination with insulin and/or metformin and/or pioglitazone. An indirect comparison demonstrated similar efficacy to another DPP-4 inhibitor. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question restricted to use:**<br>– **as monotherapy in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.**<br>– **as combination therapy with a sulphonylurea and metformin when diet and exercise plus dual therapy does not provide adequate glycaemic control.**<br>**Use of linagliptin in combination with insulin is not recommended by SMC and is non-Formulary.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| Medicine name: | **Linagliptin plus metformin tablets (Jentadueto®)**<br>*Boehringer Ingelheim* | Reason for consideration: | **New combination** |
|---|---|---|---|
| Indication under review: | **Treatment of adult patients with type 2 diabetes mellitus:**<br>– **as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin.**<br>– **in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.** | | |
| SMC/ HIS reference: | **SMC 841/13 [Abbreviated Submission]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and these fixed-doses are considered appropriate. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question restricted to restricted to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and these fixed-doses are considered appropriate and where there is demonstrable compliance issues with the separate constituents.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| | | | |
|---|---|---|---|
| Medicine name: | **Pegylated interferon alfa-2b pre-filled pen (ViraferonPegol®)**<br>*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] [Deferred decision]** | | |
| 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: | **Included in the GGC Paediatric Formulary for the indication in question restricted to specialist use.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| | | | |
|---|---|---|---|
| Medicine name: | **Somatropin (Saizen®)**<br>*Merck Serono Ltd* | Reason for consideration: | **New formulation** |
| Indication under review: | **Growth failure or growth disturbance in children and adolescents and growth hormone replacement in adults with pronounced deficiency (see SMC advice for full indication details).** | | |
| SMC/ HIS reference: | **SMC 737/11 [Abbreviated Submission] [Deferred decision]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland (Total Formulary)** | | |
| SMC/HIS restriction and comments: | This new formulation has been shown to be bioequivalent to the previously available freeze-dried formulation and is available at an equivalent cost. It is in a ready to use cartridge and does not require reconstitution. | | |
| FND recommendation: | **Included in the GGC Paediatric Formulary for the indication in question.**<br>**The treatment of growth disturbance in short children born small for gestational age and who have failed to show catch-up growth by 4 years of age or later is restricted to initiation and monitoring by a paediatrician with expertise in managing childhood growth disorders and growth hormone therapy.** | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| | | | |
|---|---|---|---|
| Medicine name: | **Vildagliptin tablets (Galvus®)**<br>*Novartis* | Reason for consideration: | **New indication** |
| Indication under review: | **Treatment of type 2 diabetes mellitus in adults as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.** | | |
| SMC/ HIS reference: | **SMC 826/12 [Full Submission]** | | |
| Summary of advice: | **Accepted for restricted use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | SMC restriction: for use in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.<br><br>In two comparator controlled studies the non-inferiority of vildagliptin to first-line oral anti-diabetic agents was not shown. A network meta-analysis demonstrated similar reductions in HbA1c at 24 weeks for vildagliptin versus another dipeptidyl peptidase 4 (DPP-4) inhibitor. | | |
| FND recommendation: | **Included in the GGC Total Formulary for the indication in question restricted to use in patients for whom both metformin and sulphonylureas are inappropriate due to contraindications or intolerance.** | | ✓R |
| ADTC Decision 18/02/13 | **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 3: Medicines accepted by SMC – Not included in Formulary

| | | | |
|---|---|---|---|
| Medicine name: | **Palonosetron capsules (Aloxi®)**<br>*Sinclair IS Pharma* | Reason for consideration: | **New formulation** |
| Indication under review: | **Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.** | | |
| SMC/ HIS reference: | **SMC 838/13 [Abbreviated Submission]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | At recommended licensed doses the soft capsule formulation has been shown to be clinically non-inferior to the intravenous formulation and is cost neutral.<br><br>SMC has previously accepted palonosetron intravenous injection for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. | | |
| FND recommendation: | **Not included in the GGC Adult Formulary for the indication in question following consultation with the Regional Cancer Advisory Group because the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question.** | | ✘ |
| ADTC Decision 18/02/13 | **AGREED** | | |

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

| | | | |
|---|---|---|---|
| Medicine name: | **Ulipristal acetate tablets (Esmya®)**<br>*PregLem Ltd* | Reason for consideration: | **New indication** |
| Indication under review: | **Pre-operative treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to three months.** | | |
| SMC/ HIS reference: | **SMC 834/13 [Full Submission]** | | |
| Summary of advice: | **Accepted for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | Ulipristal was superior to placebo and non-inferior to a gonadotrophin releasing hormone (GnRH) agonist for reducing uterine bleeding in pre-operative women with uterine fibroids and excessive bleeding | | |
| FND recommendation: | Ⓢ **Included in the GGC Total Formulary for the indication in question restricted to specialist initiation.** | | ✓ |
| ADTC Decision 18/02/13 | **Not included in the GGC Adult Formulary for the indication in question pending further consultation with the specialists to ascertain if they wish this medicine on the Formulary.** | | ✘ |

## Section 5: Medicines not recommended by SMC

| | | | |
|---|---|---|---|
| Medicine name: | **Brentuximab vedotin infusion (Adcetris®)**<br>*Takeda UK Ltd* | Reason for consideration: | **New medicine** |
| Indication under review: | **Treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):**<br>– **following autologous stem cell transplant (ASCT) or**<br>– **following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option and treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).** | | |
| SMC/ HIS reference: | **SMC 845/12 [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

| Medicine name: | **Decitabine infusion (Dacogen®)**<br>*Janssen-Cilag Ltd* | Reason for consideration: | **New medicine** |
|---|---|---|---|
| Indication under review: | **Treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.** | | |
| SMC/ HIS reference: | **SMC 846/12 [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: | **Etoricoxib tablets (Arcoxia®)**<br>*Janssen-Cilag Ltd* | Reason for consideration: | **New medicine** |
|---|---|---|---|
| Indication under review: | **Short-term treatment of moderate pain associated with dental surgery.** | | |
| SMC/ HIS reference: | **SMC 847/12 [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: | **Hydrocortisone tablets (Plenadren®)**<br>*ViroPharma Ltd* | Reason for consideration: | **New presentation** |
|---|---|---|---|
| Indication under review: | **Treatment of adrenal insufficiency in adults.** | | |
| SMC/ HIS reference: | **SMC 848/12 [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: | **Ivacaftor tablets (Kalydeco®)**<br>*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 [Full Submission]** | | |
| Summary of advice: | **Not recommended for use in 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.<br><br>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.<br><br>The licence holder had indicated their intention to resubmit. | | |
| FND recommendation: | **Not included in the GGC Adult Formulary for the indication in question.**<br><br>**In response to advice from the Scottish Government, access to this medicine for suitable patients would be via the Group Patient Request process.** | | ✘ |

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: | **Mannitol inhalation powder hard capsule (Bronchitol®)**<br>*Pharmaxis Ltd.* | Reason for consideration: | **New formulation** |
| Indication under review: | **Treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care.** | | |
| SMC/ HIS reference: | **SMC 837/13 [Full Submission]** | | |
| Summary of advice: | **Not recommended for use in NHS Scotland** | | |
| SMC/HIS restriction and comments: | In two phase III clinical studies in patients with CF, inhaled mannitol was superior to a control treatment (a sub-therapeutic dose of inhaled mannitol) measured by absolute change in forced expiratory volume in one second ($FEV_1$) over 26 weeks.<br><br>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: | **Tadalafil tablets (Cialis®)**<br>*Eli Lilly and Company Limited* | Reason for consideration: | **New indication** |
| Indication under review: | **Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.** | | |
| SMC/ HIS reference: | **SMC 849/12 [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.** | | ✘ |

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

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

| | | | |
|---|---|---|---|
| Medicine name: | **Rituximab (MabThera®)**<br>*Roche* | Reason for consideration: | **New indication** |
| Indication under review: | **First-line treatment of stage III-IV follicular lymphoma.** | | |
| SMC/ HIS reference: | **NICE MTA243 [Deferred decision]** | | |
| Summary of advice: | **Recommended as a treatment option** | | |
| SMC/HIS restriction and comments: | Rituximab, in combination with:<br>– cyclophosphamide, vincristine and prednisolone (CVP)<br>– cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)<br>– mitoxantrone, chlorambucil and prednisolone (MCP)<br>– cyclophosphamide, doxorubicin, etoposide, prednisolone and interferon-α (CHVPi) **or**<br>– chlorambucil<br>is recommended as an option for the treatment of symptomatic stage III and IV follicular lymphoma in previously untreated people. | | |
| FND recommendation: | **Advice is noted. No changes are required to the GGC Adult Formulary or regional protocols.** | | ✓R |
| ADTC Decision 18/02/13 | **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: | **Desogestrel 75microgram tablets (Cerelle®)** *Consilient Health* | Indication: | **Contraception** |
|---|---|---|---|
| Reason for consideration: | **New Drug Assessment** | SMC decision: | **N/A** |
| FND recommendation, restrictions on use and comments: **Included in the GGC Total Formulary for the indication in question restricted to use in patients in whom oestrogen containing contraceptives are not tolerated or are contra-indicated.** | | | ✓R |
| ADTC Decision 18/02/13 | **AGREED** | | |

| Medicine name: | **Micafungin infusion (Mycamine®)** *Astellas* | Indication: | **Treatment of invasive candidiasis in non haemato-oncology patients (as per guideline).** |
|---|---|---|---|
| Reason for consideration: | **Formulary Appeal** | SMC decision: | **SMC 497/08 [Full submission]** |
| FND recommendation, restrictions on use and comments: **Ⓢ Included in the GGC Total Formulary for the indication in question restricted to specialist use in the treatment of invasive candidiasis in adults, elderly, and children (including neonates) in accordance with local guidance.**<br><br>**Use for the treatment of oesophageal candidiasis, or for the prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have for 10 or more days is not recommended by SMC and is non-Formulary.** | | | ✓R |
| ADTC Decision 18/02/13 | **AGREED subject to inclusion that the licence for this medicine is for when other treatment options are not appropriate.** | | |

| Medicine name: | **Temocillin injection (Negaban®)** *Eumedica* | Indication: | **Proven gram negative bacteraemia with ESBL and AmpC betalactamase producing bacteria** |
|---|---|---|---|
| Reason for consideration: | **Formulary Appeal** | SMC decision: | **Pre-dates SMC** |
| FND recommendation, restrictions on use and comments: **Ⓢ Included in the GGC Total Formulary for the indication in question restricted to specialist use only on the advice of a microbiologist or an infectious disease physician as second line therapy in severely-ill patients with confirmed ESBL- or AmpC related infections.** | | | ✓R |
| ADTC Decision 18/02/13 | **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