CONFIRMED

MINUTES OF THE MEETING OF THE FIFE AREA DRUG AND THERAPEUTICS COMMITTEE HELD AT 12.30PM ON WEDNESDAY 17 FEBRUARY 2016 IN THE BOARD ROOM, HAYFIELD CLINIC, KIRKCALDY.

Present: Dr F Elliot (Chair)  
Dr S Ainsworth  
Dr R Cargill  
Dr I Gourley  
Dr D Griffith  
Mr D Mitchell  
Mr I Mohammed  
Dr A McGovern  
Dr J McLaren  
Mrs E McPhail  
Dr D Reid  
Mr E Reid  
Dr S Rogers  
Mrs S Tyson

In attendance: Mrs S MacDonald (minutes)

1 APOLOGIES FOR ABSENCE

Dr Elliot welcomed Dr David Griffith, Consultant Microbiologist to the meeting and introductions took place round the table.

Apologies for absence were noted from Dr L Anderson, Mr Scott Garden and Ms Janette Owens.

2 MINUTES OF PREVIOUS MEETING

The minutes of the meeting held on 16 December 2015 were confirmed as a true record.

3 SUMMARY OF ACTION POINTS FROM DECEMBER 2015 MEETING

The summary of action points was updated.

4 DECLARATION OF INTERESTS

A personal specific declaration of interest from a submitting clinician was noted in relation to Guanfacine (Intuniv®). A non-personal non-specific declaration of interest from a submitting clinician was noted in relation to Tolvaptan (Jinarc®). (Agenda item 10.2)
5 ADTC SUB-GROUP UPDATE REPORTS

5.1 Non-Medical Prescribing Group

No report available.

5.2 Prescribing and Formulary Development Group

Mr Mohammed introduced the six month update report submitted by the Prescribing and Formulary Development Group.

The ADTC noted the achievements since the last report including review of Formulary Section 3 Respiratory and associated guidelines and the work plan for the next six months.

The ADTC noted the current issues including the approval and authorisation of Shared Care Protocols; continuing pressures to meet drug budgets and efficiency savings in primary care; ongoing issues with requests to prescribe non-formulary products from hospital departments/specialties and potential changes to the role and remit of the group on the establishment of the Formulary Committee.

5.3 Antimicrobial Management Team

Dr Griffiths introduced the update report submitted by the Antimicrobial Management Team.

The ADTC noted that the first meeting of the AMT with Dr Griffiths as Chair has been convened for the end of February. Various work streams have been ongoing and reviews of several primary care and secondary antimicrobial prescribing guidelines undertaken. The Paediatric Antibiotic Guidance has been reviewed and a draft has been produced for consultation.

The ADTC noted the issue around antimicrobial pharmacist support due to impending maternity leave of the Acute Services antimicrobial pharmacist and the resignation of the Primary Care antimicrobial pharmacist.

5.4 Prescribing Efficiency Group

Dr Elliot provided a verbal update on behalf of the Prescribing Efficiency Group. Prescribing efficiency work is continuing across Primary and Secondary Care. Prescribing efficiency savings for 2015/16 are on target to reach £600K. Further work is proposed which is predicted to result in increased prescribing efficiencies for 2016/17.

The Prescribing Efficiency Group is being restructured and the proposal is that two separate groups will be established. Further information on membership of the groups will be brought to the ADTC in due course.
Mrs McPhail introduced the Shared Care Agreements for Medicines - Policy and Procedures and briefed the ADTC on the background to this. A working group chaired by Mrs McPhail was established to review the current position regarding shared care arrangements within NHS Fife. The group agreed that the development of a policy and procedures for the Shared Care of Medicines in NHS Fife was a fundamental part of the process. A draft policy has been written which defines the circumstances under which medicines will be considered appropriate for shared care and provides clarity around the individual roles and responsibilities of clinicians, patients and carers. ADTC members were asked to review and support the introduction of the policy and associated appendices including the template for developing a Shared Care Agreement. Once the policy is adopted the intention would be that any new proposed Shared Care Agreements would be deferred to the Managed Service Drug & Therapeutics Committee for initial consideration and approval in terms of clinical content. Shared Care Agreements would then be forwarded to the GP Clinical Steering Group for approval from a GP perspective. The Shared Care Agreement would then be endorsed at the following ADTC meeting and once approved uploaded onto the relevant section of the ADTC website.

The following comments were received from the ADTC:

- Mrs Tyson highlighted lack of clarity on the eligibility criteria for a shared care agreement and whether one or all of the criteria listed would require to be met. Mrs McPhail advised that the eligibility criteria would be dependent on the medical condition and drug prescribed. It was suggested that potential re-wording to clarify this be explored.
- Dr Cargill highlighted different types of monitoring that may be required for a drug e.g. drug toxicity monitoring, drug efficacy monitoring and disease activity monitoring.
- Mr E Reid queried the review date for Shared Care Agreements and whether this would be determined on an individual level. Mr Mohammed highlighted that current Shared Care Protocols have a review date of three years.
- Mr Reid suggested that a statement on yellow card monitoring be included.
- Dr Gourley highlighted the shared care agreement process in NHS Tayside and the importance of the General Practitioner receiving a copy of the shared care agreement form each time a shared care agreement is proposed.
- Mrs Tyson suggested the addition of a section regarding patients not attending for monitoring.
- The word “side” is missing from the third bullet point in the eligibility criteria.
- A typographical error in appendix 3 was noted (in the second box, “British” has been mis-spelt).

The ADTC requested that the comments be considered by the original
short-life working group. An updated version to be brought to a forthcoming ADTC meeting for approval.

The ADTC agreed that the policy and associated appendices be piloted to determine whether any potential issues are identified and any revisions required to the documentation. It was proposed that methotrexate would be a suitable example for testing the process as it is used by a number of specialties with different monitoring requirements.

**7 HIS REPORT PUBLIC ENGAGEMENT WITH ADTCs**

The Healthcare Improvement Scotland report “Approaches to Public Involvement in NHS Board Area Drug and Therapeutics Committees in NHSScotland” was noted. It was noted that NHS Fife does not have public representation on the Committee. Mrs McPhail advised that there have previously been a number of unsuccessful attempts to recruit a member of the public. It was noted that the HIS report contains helpful information on how to approach public representation groups for input. Mrs McPhail and Mr Mohammed to again explore the issue of public representation on the ADTC.

**8 GOVERNANCE – NHS FIFE MICROGUIDE APP FOR ANTIMICROBIAL GUIDANCE**

Dr Griffiths introduced the paper produced by Niketa Platt, Antimicrobial Pharmacist on the use of the Microguide app to host NHS Fife antimicrobial guidance. The paper details the rationale for the adoption of the Microguide app and clarifies the governance procedures in place.

It was noted that SAPG are proposing the development of a national antimicrobial prescribing guidance app but there is no timeframe for this at present.

The ADTC noted the report and was reassured that robust governance processes are in place for the management of the data held within the app.

**9 HIS ADVICE - PATIENT SELF-MONITORING OF ORAL ANTICOAGULATION THERAPY**

Dr Rogers introduced the report prepared by Mr David Binyon, Primary Care Development Pharmacist, in response to Healthcare Improvement Scotland (HIS) Evidence Note 57: Is patient self-monitoring of oral anticoagulation therapy safe, efficacious and cost effective? The ADTC noted that NHS Fife have been providing a service in line with HIS advice for a number of years. A training and assessment programme to support patients to self-manage their anticoagulant therapy is currently provided in Glenrothes and North East Fife and one practice in West Fife. Mr Binyon has offered to provide the necessary training to extend the service to other parts of Fife.

The ADTC noted the recommendations of HIS Evidence Note 57 and supported the continued use of anticoagulant self-management for
suitable patients through the extension and further development of the existing service.

10 SMC

10.1 Tolvaptan Draft Protocol

Mr Mohammed introduced the draft protocol for the use of tolvaptan for autosomal dominant polycystic kidney disease (ADPKD). The protocol is based on a document provided by Albert Ong (Professor in Renal Medicine at Sheffield Kidney Institute and a leading nephrologist in ADPKD) and has been adapted for use in NHS Fife. The protocol gives clear recommendations on when to initiate tolvaptan in patients with ADPKD in NHS Fife and when treatment should be stopped or urgently reviewed. All patients being considered for tolvaptan should be seen by a renal physician and remain under follow up for the duration of the treatment and the responsibility for blood monitoring should be undertaken by the renal unit. Tolvaptan will only be prescribed by renal physicians who have undertaken the recognised training.

The following comments were received from the ADTC:

- Tolvaptan should be prescribed by brand name as there are two tolvaptan products.
- The protocol refers to checking baseline LFTs (AST/ALT/Bilirubin). Reference to AST should be removed from the protocol as this test is not carried out within NHS Fife.

The final version of the protocol for the use of tolvaptan for autosomal dominant polycystic kidney disease to be tabled at the Managed Service Drug & Therapeutics Committee in due course for approval.

10.2 SMC Recommendations issued December 2015 and January 2016

The ADTC decisions are recorded in Appendix 1.

Ulipristal acetate (Esmya®) SMC 1128/16

Ulipristal acetate (Esmya®) has been approved by the SMC for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

Ulipristal is currently listed in the Fife Formulary restricted to hospital use only as an oral alternative to gonadorelin analogues for the pre-operative treatment of moderate-severe uterine fibroids, course length a maximum of 3 months. The ADTC noted that there is usage in Primary Care. Mr Mohammed advised that he has contacted local specialists for their opinions on the Formulary status of ulipristal for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Feedback from local specialists is that they would wish to use ulipristal for this indication however there has been no response to specific questions regarding its status in the Fife Formulary.
Following discussion the ADTC agreed that ulipristal acetate **should not be included on the Fife Formulary** for this indication as clinicians have not responded to an invitation to apply for Formulary inclusion.

10.3 **SCAN Formulary Submissions Approved by Lothian Formulary Committee**

The ADTC decisions in relation to SCAN formulary submissions approved by Lothian Formulary Committee are recorded in Appendix 2.

10.4 **NICE Multiple Technology Appraisal (MTA) Guidance No 373 - abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis**

Mr Mohammed highlighted NICE Technology Appraisal Guidance 373 Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis. The ADTC noted that the information in NICE MTA 375 is in line with previous advice issued by SMC.

10.5 **NICE MTA Guidance 375 - adalimumab, etanercept, infliximab, certolizumab, pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed**

Dr McLaren highlighted NICE Technology Appraisal Guidance 375. Dr McLaren confirmed that the information within the NICE Guidance is in line with current practice within NHS Fife.

11 **FORMULARY**

11.1 **Updated - National Clinical Guidelines for the Treatment of HCV in Adults**

Mr Mohammed highlighted the National Clinical Guidelines for the Treatment of HCV in Adults which were reviewed and updated in December 2015. The updated guidelines provide greater clarity on the treatment regimes for the different Genotypes. Mr Mohammed has contacted the local clinical specialist and specialist pharmacist and they have confirmed that they would follow the advice within the guidelines.

The ADTC **noted** the updated National Clinical Guidelines for the Treatment of HCV in Adults.

**Updated - Hepatitis Section**

Mr Mohammed introduced the updated hepatitis section of the Fife Formulary and highlighted the changes which have been made in light of the revised National Clinical Guidelines for the Treatment of HCV in Adults.

The ADTC **approved** the updated hepatitis section of the Fife Formulary.

11.2 **Fife Formulary Submission - Renacet®**
Mr Mohammed took the Committee through the formulary submission for Renacet® for the treatment of hyperphosphataemia.

The ADTC noted the following:

- There are two calcium acetate products currently listed on the Fife Formulary, Phosex® and Phoslo®.
- Phoslo® has been discontinued and having an alternative calcium acetate product on the Formulary would provide patients with a choice and aid patient compliance with the treatment regime.

The ADTC **approved the request to include Renacet® in the Fife Formulary** for the treatment of hyperphosphataemia. Restricted to initiation on the advice/recommendation of a specialist.

11.3 Fife Formulary Submission - Zumenon® Tablets

Mr Mohammed advised that after further discussions with the local specialist it has been decided to withdraw the Formulary submission for Zumenon® oestrogen only HRT. The Formulary choice oestrogen HRT product is Elleste Solo®.

11.4 Fife Formulary Submission - Salofalk® Granules

Mr Reid advised that the formulary submission for Salofalk Granules for the treatment of acute episodes and maintenance of remission of ulcerative colitis has been withdrawn.

11.5 Fife Formulary Submission - Salofalk® Foam Enemas

Mr Reid introduced the Formulary Submission for Salofalk® Foam Enema for the treatment of ulcerative colitis of the sigmoid colon and rectum.

The ADTC noted the following:

- The current Formulary choice for the proposed indication is Asacol® Foam Enema.
- One of the principal reasons for the Formulary submission had been due to supply issues with Asacol® however the supply issues have now been resolved.
- Salofalk® Foam Enema has a lower foam volume compared with Asacol® Foam Enema which may potentially aid patient adherence however there is currently lack of robust evidence to support this.
- Salofalk® Foam Enema is on hospital contract however Asacol® Foam Enema is a more cost effective treatment option for use in Primary Care. The level of prescribing in Primary Care and Secondary Care should be explored.

Subject to clarification on the level of prescribing in Primary/Secondary Care the ADTC **did not approve the request to include Salofalk Foam Enema in the Fife Formulary** for the treatment of ulcerative colitis of the...
sigmoid colon and rectum.

11.6 **Fife Formulary Submission - Menthol in Aqueous Cream (Dermacool®)**

Mr Reid introduced the Formulary Submission for Menthol in aqueous cream (Dermacool®) for the treatment of pruritis.

The ADTC noted the following:

The current menthol in aqueous cream choice for the proposed indication is a non-Formulary unlicensed medicinal product. Dermacool® is a licensed product, a more cost effective treatment option and is available in a variety of strengths.

The ADTC **approved the request to include Dermacool® in the Fife Formulary** for the treatment of pruritis.

12 **GUIDELINES**

12.1 **New - Treatment Options for People with Heart Failure Reduced Ejection Fraction**

Dr Cargill introduced the Treatment Options for People with Heart Failure with Reduced Ejection Fraction Guidance which was developed by the Heart Disease MCN Heart Failure Subgroup.

Following discussion the ADTC noted the following:

The use of ivabradine in patients with heart failure with a heart rate greater than 70 beats per minute is recommended within the Guidance. This is in line with the European Society of Cardiology Guidelines for the Management of Heart Failure however ivabradine is licensed in the UK in patients with heart failure with a heart rate ≥ 75 beats per minute and has been approved by the SMC for initiation only in patients whose resting heart rate remains ≥ 75 beats per minute despite optimal standard therapy. The ADTC agreed that the advice within the Guidance in relation to the use of ivabradine in patients with heart failure should be in line with the UK licence and ivabradine should only be used in patients with heart failure with a heart rate ≥ 75 beats per minute.

The Committee provided the following additional comments:

- Consideration should be given to providing patients with Medicines Sick Day Rules Cards.
- Valsartan and Trandolapril are mentioned in the tables; Valsartan is a non-Formulary medicine and Trandolapril is restricted after recent MI in patients with left ventricular dysfunction.
- In the Beta-blocker Flow Chart the three boxes at the bottom should be re-ordered to read alphabetically from left to right. In the Nebivolol Titration box, >250mmol/l should be changed to >250 µmol/l.

The ADTC requested that the above comments should be considered by the Heart Disease MCN Heart Failure Subgroup and the guidance
document amended accordingly. A final version of the guidance to be forwarded to Mr Mohammed for approval at a forthcoming ADTC meeting. Dr Cargill and Mr Mohammed to feed back to the Heart Disease MCN Heart Failure Subgroup.

12.2 Updated - Appendix 7D - Management of LUTS Pathway

Mrs Tyson introduced updated Fife Formulary Appendix 7D - Management of Male LUTS Pathway and highlighted the changes.

The ADTC noted the changes and approved the updated Fife Formulary Appendix 7D - Management of Male LUTS Pathway.

12.3 Updated - Appendix 7C - Emergency Contraception

Mr Mohammed introduced updated Fife Formulary Appendix 7C - Emergency Contraception and highlighted the changes. The Guidance has been updated to reflect recent changes in the Faculty of Sexual and Reproductive Health UK Guidance.

The ADTC noted the changes and approved the updated Fife Formulary Appendix 7C - Emergency Contraception.

12.4 Updated - Penicillin Allergy

Dr Griffith introduced the updated Penicillin Allergy Guidance and highlighted the changes.

The ADTC noted the changes and approved the updated Penicillin Guidance.

12.5 Updated - IV to Oral Switch Therapy

Dr Griffith introduced the updated IV to Oral Switch Therapy Guideline. The ADTC noted the change to the gentamicin information to refer prescribers to the gentamicin guidance.

The ADTC approved the updated IV to Oral Switch Therapy Guideline.

12.6 Updated - Gentamicin Guidelines

Dr Griffith introduced the updated Once-Daily Gentamicin Guideline for Adults. The ADTC noted that the expected duration of treatment has been removed to avoid any potential for misinterpretation with the information given in the gentamicin calculator.

The ADTC approved the updated Once-Daily Gentamicin Guideline for Adults.

12.7 Updated - Vancomycin Guidelines

Dr Griffith introduced the Vancomycin Intermittent (Pulsed) Guideline for Adults. The ADTC noted that the Guideline was due for review however
no changes were required.

The ADTC approved the updated Vancomycin Intermittent (Pulsed) Guideline for Adults.

13 ITEMS FOR NOTING

13.1 Individual Patient Treatment Requests - Latest Submissions

The updated table of Individual Patient Treatment Requests was noted.

13.2 MHRA Drug Safety Updates

The MHRA Drug Safety Updates for December 2015 and January 2016 were noted.

13.3 ADTC Bulletin - November - December 2015

The ADTC Bulletin November - December 2015 was noted.

13.4 Fife Medicines Focus December 2015 and January 2016

Fife Medicines Focus issues 24 (December 2015) and 25 (January 2016) were noted.

14 POINTS FOR RAISING AT CLINICAL GOVERNANCE COMMITTEE

Dr Elliot invited comments from the ADTC in relation to any pertinent points or issues that should be raised at the Clinical Governance Committee.

It was agreed that the following should be highlighted to the Clinical Governance Committee:

- Patient self-monitoring of oral anticoagulation therapy
- NHS Fife Microguide App for Antimicrobial Guidance
- NHS Fife Shared Care Agreements Policy

15 ANY OTHER COMPETENT BUSINESS

a Minutes of Other ADTC Meetings
a.1 Lothian Formulary Committee: Minutes of meeting 16 December 2015. For information.
a.2 Tayside Drug & Therapeutics Committee: Minutes of meeting 7 December 2015. For information.

b Minutes of MCN Prescribing Sub-Groups
There have been no meetings since the date of the last ADTC.

c Date of Next Meeting
The next meeting is to be held on Wednesday 20 April 2016 at 12.30pm in the Board Room, Hayfield Clinic, Kirkcaldy. (The deadline for submission of papers to be considered for the agenda is 4 April 2016.)
Apologies for meeting to be notified to Sandra MacDonald by 4 April 2016.)
## Scottish Medicines Consortium Recommendations

### December 2015 1114/15

**Tolvaptan 15mg, 30mg, 45mg, 60mg and 90mg tablets (Jinarc®)
Otsuka Pharmaceuticals (UK) Ltd**

To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease in adults with chronic kidney disease (CKD) stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.

**Comparator Medicines:**
There are no relevant comparators.

**Indication under review:**
To slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease.

In a phase III placebo-controlled study tolvaptan, after 3 years, had significantly slowed the rate of disease progression as measured by impact on the rate of increase in total kidney volume (TKV) in ADPKD patients who were deemed to be at high risk of disease progression and had relatively preserved renal function. The study inclusion criteria included (list not exhaustive): age 18 to 50 years old, TKV ≥750ml and creatinine clearance ≥60ml/minute.

This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tolvaptan. This advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.

This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

**Decision of ADTC:**
Included on the Fife Formulary.

**Rationale:**
Due to different formulations of tolvaptan being licensed for different indications prescribed by brand name only.

Hospital use only.

### December 2015 1115/15

**Ustekinumab 45mg solution for injection and prefilled syringe (Stelara®)
Janssen Ltd**

**Product Update**

**Indication under review:**
Treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

**SMC restriction:**
Continued treatment should be restricted to patients who achieve at least 75% improvement in their Psoriasis Area and Severity Index (PASI 75) within 16 weeks.

Ustekinumab has previously been accepted for restricted use in adults for this indication. For the small number of adolescent patients weighing >100kg that require a dose of 90mg, a 90mg prefilled syringe is available at the same price as the 45mg prefilled syringe.

**Decision of ADTC:**
Included on the Fife Formulary for the indication stated.

**Rationale:**
Hospital use only.

### December 2015 1110/15

**Dulaglutide 0.75mg and 1.5mg solution for injection in pre-filled pen (Trulicity®)
Eli Lilly and Company Ltd**

**Indication under review:**
In adults with type 2 diabetes mellitus to improve glycaemic control as add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

**Decision of ADTC:**
Decision deferred until review meeting of diabetes section is undertaken.

**Rationale:**
Not included on the Fife Formulary as clinicians do not support Formulary inclusion.
**SMC Advice - Formulary Decisions**

- **Monotherapy:** when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.
- **Add-on therapy:** in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

**Comparator Medicines:**

Medicines that may be added-on for patients inadequately controlled on two OADs include GLP-1 agonists, DPP-4 inhibitors, TZDs, SGLT-2 inhibitors and basal insulins. In practice it is likely to replace other GLP-1 agonists. This reflects the positioning proposed by submitting company.

**SMC restriction:** as part of a triple therapy in patients with inadequate glycaemic control on two oral anti-diabetic drugs, as an alternative glucagon-like peptide 1 (GLP-1) agonist option.

**Dulaglutide 1.5mg once weekly significantly reduced glycosylated haemoglobin (HbA1c) compared with a twice daily GLP-1 agonist and compared with a long-acting basal insulin analogue in patients with inadequate glycaemic control on two oral anti-diabetic drugs.**

**Dulaglutide is also indicated for adults with type 2 diabetes mellitus to improve glycaemic control as monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications. SMC has not reviewed dulaglutide in this indication and cannot recommend its use within NHS Scotland.**

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<thead>
<tr>
<th>Date</th>
<th>Product</th>
<th>Indication under review</th>
<th>SMC decision</th>
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| January 2015 (issued December 2015) 1024/15 | albiglutide 30mg and 50mg pre-filled pen (Eperzan®) GlaxoSmithKline | Treatment of type 2 diabetes mellitus in adults to improve glycaemic control 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 contraindications or intolerance.  
  - Add-on combination therapy: In combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.  
**Comparator Medicines:** The relevant comparator given the company’s positioning is the GLP-1 agonist, exenatide ER.  
Indication under review: Treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.  
As add-on combination therapy, albiglutide was superior to placebo and to some oral comparators for glycaemic control. It was inferior to an alternative GLP-1 agonist and non-inferior to insulin.  
This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of albiglutide. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.  
Albiglutide is also indicated for adults with type 2 diabetes mellitus to improve glycaemic control as monotherapy when diet and exercise alone does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance. SMC has not reviewed albiglutide in this indication and cannot recommend its use within NHS Scotland.  
| Not included on the Fife Formulary as clinicians do not support Formulary inclusion.  
| Decision deferred until review meeting of diabetes section is undertaken. |

| December 2015 1109/15 | netupitant/palonosetron 300mg/0.5mg, hard capsule (Akynzeo®) Chugai Pharma UK Limited | Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.  
**Indication under review:** in adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.  
**Not included on Fife Formulary pending protocol.**  
| Await SCAN submission and decision by Lothian Formulary Committee.  
| Usage locally would |
### SMC Advice - Formulary Decisions

<table>
<thead>
<tr>
<th>Date</th>
<th>Product</th>
<th>Indication</th>
<th>SMC Restriction</th>
<th>Notes</th>
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<tr>
<td>December 2015 482/08</td>
<td>sorafenib 200mg film-coated tablets (Nexavar®) Bayer plc</td>
<td>Treatment of hepatocellular carcinoma</td>
<td>SMC restriction: in patients with advanced hepatocellular carcinoma who have failed or are unsuitable for surgical or loco-regional therapies.</td>
<td>This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sorafenib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</td>
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<td>January 2016 1128/16</td>
<td>ulipristal acetate, 5mg, tablet (Esmya®) Gedeon Richter (UK) Ltd</td>
<td>for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.</td>
<td>Ulipristalacetate (Esmya®) is accepted for use within NHS Scotland.</td>
<td>Not included on Fife Formulary for this indication as clinicians have not responded to an invitation to apply for Formulary inclusion for the indication stated.</td>
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**Comparator Medicines:**
- Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

**SMC Restriction:** prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.

In patients receiving a first course of highly emetogenic cisplatin-based chemotherapy, treatment with netupitant/palonosetron plus dexamethasone resulted in a significantly higher proportion of patients achieving no emesis and no breakthrough medication compared with palonosetron plus dexamethasone.

This advice takes account of the benefits of Patient Access Scheme (PAS) that improves the cost-effectiveness of netupitant/palonosetron. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

**Comparator Medicines:**
- Best supportive care.
- Ulipristal acetate controlled uterine bleeding in approximately three-quarters of patients with symptomatic uterine fibroids after four intermittent treatment courses.

**Comparator Medicines:**
- Ulipristal is the only treatment licensed for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

**Comparator Medicines:**
- Best supportive care.

**SMC Restriction:** prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.
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<tr>
<td><strong>January 2016 1124/16</strong></td>
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<tr>
<td><strong>Golimumab (Simponi)</strong> is accepted for use within NHS Scotland.**</td>
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**Indication under review:** Treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

Golimumab, compared to placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis.

This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of golimumab. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

**Comparator Medicines:** Other TNF-α inhibitors licensed for this indication are etanercept, adalimumab and certolizumab pegol.

**Included on the Fife Formulary for the indication stated.**

2nd line agent after certolizumab or where a monthly inj. would be clinically appropriate.

Hospital use only.

**SMC golimumab (Simponi)**

| **January 2016 1123/16**          |
| **Guanfacine (Intuniv)** is accepted for use within NHS Scotland.** |

**Indication under review:** Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.

Two phase III studies in children and adolescents aged 6 to 17 years with ADHD demonstrated that guanfacine improved the symptoms of ADHD compared with placebo.

This advice adds guanfacine (Intuniv) as an alternative non-stimulant to atomoxetine.

Restricted to monotherapy use in patients where atomoxetine is ineffective or not tolerated.

Managed service specialist use only.

**SMC guanfacine hydrochloride (Intuniv)**

| **January 2016 1022/16**          |
| **Panobinostat (Farydak)** is accepted for use within NHS Scotland.** |

**Indication under review:** In combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent.

In patients with relapsed or relapsed and refractory multiple myeloma, panobinostat in combination with bortezomib plus dexamethasone was associated with a significant benefit in progression-free survival (PFS) compared with bortezomib plus dexamethasone. The treatment effect of the panobinostat containing regimen on PFS was greater in the subgroup of patients’ representative of the licensed indication.

**Included on the Fife Formulary for the indication stated.**

Hospital use only.

**SMC panobinostat (Farydak)**
<table>
<thead>
<tr>
<th>Date</th>
<th>Code</th>
<th>Medication Description</th>
<th>Recommendation</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2016</td>
<td>114/04</td>
<td>lenalidomide plus dexamethasone</td>
<td>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of panobinostat. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.</td>
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</tr>
<tr>
<td>January 2016</td>
<td>114/04</td>
<td>fulvestrant, 250mg, solution for injection (Faslodex®)</td>
<td>fulvestrant (Faslodex®) is accepted for use within NHS Scotland.</td>
<td>Not included on Fife Formulary pending protocol.</td>
</tr>
<tr>
<td>February 2016</td>
<td>112/09</td>
<td>AstraZeneca UK Limited</td>
<td></td>
<td>Await SCAN submission and decision by Lothian Formulary Committee.</td>
</tr>
<tr>
<td>January 2016</td>
<td>114/04</td>
<td>Resubmission</td>
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<td>For the treatment of postmenopausal women with oestrogen receptor positive (ER+), locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.</td>
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<td>January 2016</td>
<td>112/09</td>
<td>eculizumab 300mg concentrate for solution for infusion (Soliris®)</td>
<td>eculizumab (Soliris®) is not recommended for use within NHS Scotland.</td>
<td>Not recommended.</td>
</tr>
<tr>
<td>March 2016</td>
<td>767/12</td>
<td>Alexion Pharma UK Ltd.</td>
<td></td>
<td>Requires submission and approval of an IPTR before prescribing.</td>
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<td>January 2016</td>
<td>114/04</td>
<td>Comparator Medicines:</td>
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<td>March 2016</td>
<td>767/12</td>
<td>Axion Pharma UK Ltd.</td>
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<td>Requires submission and approval of an IPTR before prescribing.</td>
</tr>
<tr>
<td>January 2016</td>
<td>112/09</td>
<td>pixantrone (Pixuvri®) 29 mg power for concentrate for solution for infusion</td>
<td>pixantrone (Pixuvri®) is not recommended for use within NHS Scotland.</td>
<td>Not recommended.</td>
</tr>
<tr>
<td>March 2016</td>
<td>112/09</td>
<td>CTI Life Sciences Ltd</td>
<td></td>
<td>Requires submission and approval of an IPTR before prescribing.</td>
</tr>
<tr>
<td>January 2016</td>
<td>1139/16</td>
<td>Non SMC submission</td>
<td></td>
<td>Company non-submission</td>
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<tr>
<td>January 2016</td>
<td>1139/16</td>
<td>teduglutide (Revestive®) 5mg power and solvent for solution for injection</td>
<td>teduglutide (Revestive®) is not recommended for use within NHS Scotland.</td>
<td>Company non-submission</td>
</tr>
<tr>
<td>March 2016</td>
<td>1138/16</td>
<td>NPS Pharma UK Ltd</td>
<td></td>
<td>Requires submission and approval of an IPTR before prescribing.</td>
</tr>
</tbody>
</table>
**SMC Advice - Formulary Decisions**

| Non SMC submission | Indication under review: For the treatment of adult patients with Short Bowel Syndrome. 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. | Approval of an IPTR before prescribing. | SMC teduglutide (Revestive) |

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**Summary of Approved Lothian Formulary Committee Decisions for SCAN Medicines November 2015 - February 2016**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SMC Advice</th>
<th>Place in therapy</th>
<th>Lothian formulary Committee Decision</th>
<th>Add to Fife Formulary Yes / No Rationale</th>
</tr>
</thead>
</table>
| September 2015 1077/15 radium-223 dichloride (Xofigo®) is accepted for use within NHS Scotland.  
Indication under review: for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.  
In a randomised phase III study of adult men with castration-resistant prostate cancer with symptomatic bone metastases and no known visceral metastases, treatment with radium-223 dichloride was associated with a significant improvement in overall survival compared to placebo.  
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of radium-223 dichloride. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.  
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. | Will be considered in patients when bone pain is the predominant symptom and patient progressing or not appropriate for other systemic treatments. | Included on the additional list.  
Specialist hospital use only. | No  
Patients will receive treatment in Lothian. |
<table>
<thead>
<tr>
<th>Date</th>
<th>Product</th>
<th>Acceptance Details</th>
<th>Advice Details</th>
</tr>
</thead>
</table>
| September 2015 623/10 | **trastuzumab (Herceptin®)** is accepted for restricted use within NHS Scotland.  
  **Indication under review:** in combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. It is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.  
  **SMC restriction:** for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser").  
  The addition of trastuzumab to doublet chemotherapy improved overall and progression-free survival and tumour response.  
  This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. | Will be used in combination with cisplatin and capecitabine for patients with advanced oesophago-gastric adenocarcinoma whose tumours have HER2 over-expression.  
  Will replace combination palliative chemotherapy using epirubicin, oxaliplatin and capecitabine.  
  Included on the additional list.  
  Specialist hospital use only.  
  Yes  
  Patients will be treated in Fife. |}
| September 2015 873/13 | **abiraterone acetate (Zytiga®)** is accepted for use within NHS Scotland.  
  **Indication under review:** abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.  
  In a randomised, double-blind phase III study of adult men with chemotherapy-naive mCRPC, treatment with abiraterone acetate in combination with corticosteroid was associated with a statistically significant extended progression-free survival and overall survival when compared with placebo plus corticosteroid.  
  This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone acetate. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.  
  This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. | Will be used in adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.  
  Abiraterone will be used in men who meet the above criteria and have no contraindication to abiraterone.  
  LHRH analogue will continue alongside abiraterone treatment.  
  Included on the additional list.  
  Specialist hospital use only.  
  Yes  
  Patients may be treated in Fife.  
  Currently all treated in Lothian. |
<table>
<thead>
<tr>
<th>Date</th>
<th>Approval Number</th>
<th>Product</th>
<th>Indication under review</th>
<th>SMC restriction</th>
<th>Usage</th>
<th>Patients will be treated in</th>
<th>Notes</th>
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<tbody>
<tr>
<td>October 806/12 2015</td>
<td>bevacizumab (Avastin®) is accepted for restricted use within NHS Scotland.</td>
<td>Indication under review: In combination with carboplatin and paclitaxel, for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics (FIGO) stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.</td>
<td>SMC restriction: In patients with FIGO stage IV disease</td>
<td>Addition of bevacizumab to standard chemotherapy with carboplatin and paclitaxel increased progression-free survival. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</td>
<td>Will replace patients receiving single agent paclitaxel. Included on the additional list. Specialist hospital use only.</td>
<td>No Patients will be treated in Lothian.</td>
<td></td>
</tr>
<tr>
<td>November 1097/15 2015</td>
<td>ceritinib (Zykadia®) is accepted for use within NHS Scotland.</td>
<td>Indication under review: Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.</td>
<td>In two non-comparative studies (one phase I and one phase II) of patients with advanced ALK-positive NSCLC previously treated with crizotinib, treatment with ceritinib was associated with clinically meaningful tumour responses and median overall survival of approximately 15 to 17 months. Controlled data with clinical outcomes are currently lacking. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ceritinib. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</td>
<td>Not included pending protocol. Clinicians have confirmed submission pending.</td>
<td>No Patients will be treated in Lothian.</td>
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| November 2015 615/10 | gefitinib (Iressa®) is accepted for restricted use within NHS Scotland.  
**Indication under review:** the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).  
**SMC restriction:** in patients with previously untreated locally advanced or metastatic NSCLC with activating EGFR-TK mutations i.e. as a first-line therapy.  
In patients with EGFR mutation-positive, advanced NSCLC, randomised controlled studies demonstrated an improvement in the progression-free survival and tumour response rates for those treated with gefitinib compared with platinum-doublet chemotherapy. There was no overall survival benefit demonstrated.  
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of gefitinib. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. | Not included as clinicians have not responded to an invitation to apply for Formulary inclusion for this medicine. | No Patients will be treated in Lothian. |