ADTC(M) 17/03 Minutes: 33 - 46

NHS GREATER GLASGOW AND CLYDE

Minutes of a Meeting of the Area Drugs and Therapeutics Committee held in the Boardroom, JB Russell House on Monday, 19 June 2017 at 2.00 p.m.

PRESENT

Dr S Muir (in the Chair)

Mrs J Watt Mrs A Campbell Dr A Seaton Mrs A Muir Dr J Mackenzie Dr A Taylor Dr R Hardman Dr B MacKinnon Mrs Y Semple Mr R Foot Dr K O'Neill Ms F Thomson Mrs Margaret Ryan Prof N Lannigan Mrs A Thompson Dr K McAllister

IN ATTENDANCE

Miss L Young.....Secretariat Officer

ACTION BY

33. CHAIR'S STATEMENT

The Chair reminded Members that papers and proceedings relating to SMC advice were, in some cases, confidential and should not be disclosed before the relevant embargo dates stated in the agenda.

He also reminded Members that they should make relevant declarations of interest in line with Board policy.

Members were advised not to speak with members of the press on ADTC business but to refer such enquiries to the Board press liaison office.

34. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr G Forrest, Mr G Gorman, Mrs L Hillan, Prof G McKay, Dr C Harrow, Mr D Malcolmson, Dr A Bowman, Mr A Crighton.

35. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 24 April 2017 were approved as a correct record pending the following amendments;

AREA DRUGS & THERAPEUTICS COMMITTEE: 19 JUNE 2017

- Item 23, Page 4, second para: Dr Taylor sought clarity on the wording of the last sentence in relation to no additional Primary Care monitoring. Shared Care paperwork was completed for this medicine and the reviewing group agreed that it was not suitable for Shared Care. The minute will be amended at Dr Taylor's request. The last sentence will be amended to "She reported that this medicine does not meet the criteria for shared care. There are no additional Primary Care monitoring".
- Dr Seaton submitted amendments to the antimicrobial section of the minutes to the secretary.

Amendments will be made and the Secretary will re-circulate the minutes to the Committee.

NOTED

36. MATTERS ARISING

Alirocumab/evolocumab

Following the agreed change in prescriber status for these new lipid lowering medicines, support material for GP's has been prepared to clarify the role of this new medicine class. A medicines update blog will highlight this and a link to the prescribing material included in the Formulary.

As an interim measure the lipid clinics are willing to accept filled sharps boxes for safe disposal and patients will be advised of this accordingly.

37. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) <u>Report on SMC Product Assessments</u>

Mr Foot gave a brief resume of the SMC reviews and the Formulary and New Drugs Sub-Committee's recommendations.

Members were asked to declare any interests specific or non-specific, personal or non-personal, on any of the drugs being discussed on an individual basis.

No declarations of interest were made.

See Appendix 1 for summarised decisions

38. COMMUNICATIONS SUB-COMMITTEE

Six Monthly Report

Mrs Thompson tabled the six monthly report to inform the ADTC on the work of the Communications Sub-Committee. Mrs Thompson highlighted in particular;

The Terms of Reference of the Sub-Committee were reviewed at the meeting in March 2017. A new format was proposed for approval. It was agreed that the position of Chair should be a member based in PPSU's Medicines Information department as the role sits well under their remit. Mrs Yvonne Semple will take over

as Chair from the next meeting.

At the moment there is a two tier structure of a small editorial group and a larger steering group. The focus will now be on one single group. The main editorial group will continue and will invite strategic input from other relevant parties twice per year.

Membership of the Sub-Committee will be extended and members who have left will be replaced.

Mrs Thompson provided an update on the website access statistics for blog postings. She provided a report for the period 01/12/16-31/05/17 which highlights clear peaks in usage which coincide with email alerts. Mrs Thompson highlighted that views at the weekend are increasing and there is an increase in mobile devices accessing the website. The posts on DOAC's and Tramadol have been particularly popular.

Social media feeds on Twitter and Facebook continue to be used to highlight new articles and share relevant information. It was suggested that the corporate communications team is approached to discuss retweeting tweets in order to make the page more visible and to increase followers. Mrs Thompson will contact the corporate communications team to discuss this further. Mrs Semple will produce a one page summary in order to promote/advertise the Twitter/Facebook pages. She will submit this at the next meeting.

Mrs Thompson/ Mrs Semple

The Committee acknowledged the 6 monthly report and noted the developments.

39. ANTIMICROBIAL SUB-COMMITTEE

Six Monthly Report

The Committee noted the Antimicrobial Sub-Committee 6 monthly report to inform ADTC of the work of the Sub-Committee.

The Committee noted the minutes of the last Antimicrobial Utilisation Sub-Committee.

There is a particular focus on missed doses of antibiotics. Dr Seaton reported that 6% of antibiotic doses overall were missed. It was agreed that both oral and IV missed antibiotics should be defined as of "critical importance".

There is a focus on emergency department use of antibiotics. Dr Seaton highlighted that a relatively high proportion of co-amoxiclav is used within Emergency Departments in GG&C which is disproportionate compared to inpatients. A piece of work is underway to engage with emergency departments regarding antibiotic prepacks and labelling defined courses.

SAB Management

A SAB sticker has been developed which highlights the key quality indicators from the SAPG quality indicators document. An agreement has been made that Infection Control Nurses will insert the stickers in notes. This will prompt a clinical conversation with the clinicians regarding treatment.

<u>CDI</u>

Rates reached possible nadir in the first quarter of 2017.

Primary Care

ScRAP V2 has launched. Dr Seaton provided a link in his update report.

<u>Pharma</u>

There are significant issues with antibiotic manufacturing/supply. There is low level supply of aztreonam therefore this has been removed from guidance as it is not sustainable. Supply of Piperacillin Tazobactam is low. There are recurrent issues with generic price increases. A Scriptswitch message will be created to alert GP's to the price increase.

Secondary Care

There are improvements in co-amoxiclav, Piperacillin Tazobactam (before supply issues) and meropenem across the sectors however there is ongoing increasing total volume of antibiotics in secondary care. The increase in use of Temocillin and Levofloxacin is significant.

Further work is underway to promote empirical gentamicin in a wider patient population (eGFR > 20 ml/min/1.73m² The Committee briefly discussed this changes and it was highlighted that this change will be highlighted to prescribers via Medicines Update blog. The Committee noted that multiple changes can be challenging for staff. The Committee also noted that a new empirical antimicrobial poster is being produced for dissemination in August. The Committee discussed the pros and cons of the poster as it is recognised that the information can change and therefore maintaining consistency with information in the Handbook can be challenging. The Committee acknowledged that the poster format was popular with prescribers but further consultation should be undertaken.

Secondary Care Quality Indicators

The Scottish Government has agreed new antibiotic prescribing quality indicators in order to facilitate reductions in prescribing. Cross organisational support will be required to achieve reductions.

New pieces of local and national work

Work is being carried out on the de-labelling Penicillin allergy strategy, anti fungal stewardship and antibiotic review. Dr Seaton will provide feedback when more information is available. Dr Taylor suggested that if patients are tested and no allergy is found then this should be clearly highlighted to ensure that Primary Care can mark this in the patient records. Dr Seaton assured the Committee that this would be part of the work.

Nursing AMS

Ongoing work is taking place to promote/engage the nursing stewardship workbook.

Antimicrobial prophylaxis and infective endocarditis SBAR paper

This paper was added to the agenda under AOB and discussed under this item.

The above paper was discussed and agreed at the Antimicrobial Utilisation Sub-Committee (AUC) in May 2017.

In 2008 NICE adapted their guidance regarding antimicrobial prophylaxis against infective endocarditis. This advocated that prophylaxis should no longer be provided to dental patients with cardiac lesions which put them at potential risk of IE. In July 2016 this guidance was altered to propose that prophylaxis should not be given *routinely* to patients at *increased* risk of IE undergoing dental procedures. The addition of the word "routinely" has opened the guidance up to interpretation.

Dr Seaton reported that NICE changed their guidance in 2016 because there is no evidence that you should/shouldn't consider prophylaxis in this patient group. NICE advocates that clinical judgement should be used to assess individual patient risk and the risk associated with the procedure.

To promote consistency across GGC, local GGC guidance has been produced. This was agreed at the AUC meeting in May. These will be circulated to the dental profession and Medical Director for information. The guidance also needs to be highlighted to Primary Care colleagues as it's not uncommon for Primary Care to be approached for further information. The guidance will be widely communicated within the Board.

The Committee noted the above points and noted their satisfaction with the decision.

An issue was raised in relation to high use of infusion bags, particularly at the Queen Elizabeth University Hospital. Discussions regarding changes will take place within the Senior Management Teams. Dr Seaton informed the Committee that a meeting is scheduled with Margaret McGuire, Nursing Director, next week therefore Dr Seaton will raise this issue with her at the meeting.

A brief discussion ensued on the work that is being carried out to reduce antibiotic use. Dr Seaton reported that guidance is being reviewed, durations are being reduced, clinical reviews are taking place and there is a focus on reducing course lengths in pre-packed antibiotics. Ysobel Gourlay is also in the process of speaking to Tayside who manufacture pre-packs. The logistics of supply were discussed and breaks that can occur in the supply chain.

Dr Seaton briefly reported on the information contained within the graphs.

The Committee acknowledged the 6 monthly report and noted the developments.

40. OTHER ADTC SUB-COMMITTEES

(a) Medicines Utilisation Sub-Committee

The Sub-Committee continue to view a number of guidelines.

The Sub-Committee recently reviewed the RCAG PASG Advice: Guideline for Management of Immune-related Adverse Events. Dr O'Neil reported that adverse effects from these new medicines may arise out of hours and patients may ask primary care teams for advice. Awareness of the issues and the guideline will be raised within acute and primary care.

(b) Therapeutics Sub-Committee

The dressing Formulary is now online.

(c) Prescribing Interface Sub-Committee

No update.

41. MINOR AILMENT SERVICE FORMULARY

Mr Foot presented the Minor Ailment Service Formulary which was updated in June 2017. The main changes are in relation to usage patterns and preferred products.

The aim of the Minor Ailment Service Formulary is to reduce the number of presentations to GP surgeries. The Formulary has been reviewed and endorsed by the Primary Care Management Group. The Committee noted that this is not a referral for product service. The Formulary will assist pharmacists with symptom management.

The Committee briefly discussed the pilot carried out in Inverclyde which has recently been extended. There is limited feedback to date on the programme however it appears to have been well received. Patients previously ineligible are now able to be registered and there is scope to treat some additional conditions through use of Patient Group Directions. Feedback from a similar project in Forth Valley has been positive. There is a communication plan in place for the pharmacist to make a referral to the GP. The Committee agreed that evaluation is important and local feedback would be helpful.

Mrs Thompson agreed to share the evaluation with the Committee when this is available.

42. ADTC Collaborative

ADTCC Update

EAMS Operational Guidance: Glecaprevir/Pibrentasvir for Hepatitis C

Operational Guidance for the above EAMS was issued on 1st June.

EAMS: Lack of Operational Guidance - Dupilumab

Operational guidance not issued because discussions in relation to exit strategy are ongoing. The ADTCC preference for treatment of chronic conditions to be funded until SMC accepted were not being offered by the company. It is recognised that the absence of Operational Guidance from ADTCC does not prevent health boards from accessing this medicine via EAMS.

Single National Formulary (SNF) for Scotland Stakeholders' Event (May 2017) Twelve representatives from NHSGGC attended this event.

The Committee noted the information provided.

43. NHS SCOTLAND VALPROATE PATIENT SAFETY ALERT

The Committee noted the Patient Safety Alert issued by Healthcare Improvement Scotland which highlights the resources to support the safety of girls and women who are being treated with valproate.

Mrs Semple informed the Committee that following a detailed discussion by the Committee in 2015, a blog article was created and recommendations made regarding how these resources should be used in Greater Glasgow and Clyde. The Committee agreed it would be helpful to gather information regarding how these are currently being used. Mrs Semple will take this forward and provide a summary to the Committee at a future meeting.

Mrs Semple

44. PRESCRIBING MANAGEMENT GROUP REPORT

The Prescribing Management Group reviewed the end of year financial position for 16-17 and considered the current financial position for 17-18.

The main topics for the meeting were the two recently held prescribing summits for both primary and secondary care. There had been generation of useful ideas and the Acute Services PMG is producing an action plan for the delivery of additional savings as a result. Some of the actions in acute will also result in primary care savings.

45. ANY OTHER BUSINESS

The Committee noted a paper which highlights the progress of the West of Scotland Gastroenterology Prescribing Subgroup towards developing a regional protocol for the use of 5 ASAs in the treatment of Ulcerative Colitis. The Subgroup began work to develop regional recommendation on a preferred solid oral mesalazine agent for use in the treatment and maintenance of remission of Ulcerative Colitis.

The Committee noted that all products are considered equally clinically effective, therefore the recommended first line agent was the product with the lowest medicine cost. Salofalk was the lowest priced product range therefore it was recommended that this is a first line agent in new patients. The Committee noted broad clinical support within GG&C. The Committee agreed that clear communication to GP's is required.

Following discussion the Committee agreed to support this recommendation and agreed the required Formulary changes.

46. DATE OF NEXT MEETING

Monday, 28 August 2017 - Boardroom, JB Russell House, Gartnavel Royal Hospital

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: 19/06/2017

Belimumab

Benlysta® infusion

Indication:

Add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy.

ADTC Discussion points

The SMC advice takes account the benefits of a Patient Access Scheme (PAS). The Committee noted specialists welcome this new treatment option. A protocol will be developed by the specialist service in due course.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use patients with evidence of serological disease activity (i.e. positive anti-dsDNA and low complement) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.

http://www.scottishmedicines.org.uk/files/advice/belimumab_Benlysta_Resub_FINAL_April_2017_for_website.pdf

Buprenorphine

Espranor® oral lyophilisate

Indication:

Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction.

ADTC Discussion points

The Committee noted that there is a local initiative to stop use of Suboxone and switch patients to generic buprenorphine. Local clinicians have expressed concerns that introduction of this product would undermine this piece of work. The Formulary and New Drugs Sub-Committee support not adding this product to the Formulary

ADTC Decision:

Not routinely available as local clinical experts do not wish to add the medicine to the Formulary at this time or there is a local preference for alternative medicine(s)

Local restrictions on use:

http://www.scottishmedicines.org.uk/files/advice/buprenorphine_oral_lyophilisate_Espranor_Abb_FINAL_May_2017_amended_050617_for_website.pdf

Deferasirox

Exjade® tablets

Indication:

Treatment of chronic iron overload due to frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older and treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in specific patient groups as outlined in full in the SMC advice.

ADTC Discussion points

The Committee noted the new formulation of this product. The original preparation will be withdrawn and replaced with this new formulation. The same restrictions should be applied.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use only in accordance with existing Formulary restrictions

http://www.scottishmedicines.org.uk/files/advice/deferasirox_Exjade_Abbreviated_FINAL_May_2017_Amended_050617_for_website.pdf

1246/17

Idebenone

Raxone® tablets

Indication:

Treatment of visual impairment in adolescent and adult patients with Leber's Hereditary Optic Neuropathy (LHON).

ADTC Discussion points

The SMC advice takes account the views of a PACE meeting and the benefits of a Patient Access Scheme (PAS). Small patient numbers are predicted. This new treatment option is welcomed by specialists. The Committee noted that there has been some unlicensed use and recent diagnoses have been recruited to clinical trials. Local specialists have advised that use should be restricted to consultant neuro-ophthalmologists. A discussion will take place with clinicians regarding how response is assessed and when treatment would be stopped.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to use by consultant neuro-ophthalmologists

http://www.scottishmedicines.org.uk/files/advice/idebenone Raxone FINAL April 2017 for website.pdf

Micronised progesterone

Utrogestan® vaginal capsules

Indication:

In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.

ADTC Discussion points

The SMC advice takes account the benefits of a Patient Access Scheme (PAS). The Committee noted that there are now four formulation options for progesterone. The specialist service has indicated that the three times daily administration of this product may be challenging for patients. The service will be approached to consider preferred choice(s).

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialiist use only.

http://www.scottishmedicines.org.uk/files/advice/micronised_progesterone_Utrogestan_Vaginal_FINAL_April_2017_Amended_12.04.17_for_website.pdf

Obeticholic acid

Ocaliva® tablets

Indication:

Primary biliary cholangitis (alsoknown as primary biliary cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid

ADTC Discussion points

The SMC advice takes account the views of a PACE meeting and the benefits of a Patient Access Scheme (PAS). This product can be used in combination or mono therapy. Local specialists welcome this product as an additional treatment option

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist initiation only in patients for whom alternative treatment options are not tolerated or where there has been an inadequate response

http://www.scottishmedicines.org.uk/files/advice/obeticholic acid Ocaliva FINAL May 2017 Amended 170517 for website.pdf

935/13

Cabozantinib

Cabometyx® tablets

Indication:

For the treatment of advanced renal cell carcinoma (RCC) in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy.

ADTC Discussion points

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol

http://www.scottishmedicines.org.uk/files/advice/cabozantinib Cabometyx FINAL May 2017 for website.pdf

Nivolumab

Opdivo® infusion

Indication:

As monotherapy for the treatment of advanced renal cell carcinoma after prior therapy in adults.

ADTC Discussion points

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol

http://www.scottishmedicines.org.uk/files/advice/nivolumab_Opdivo_RESUBMISSION_FINAL_May_2017_for_website.pdf

Alectinib hydrochloride

Alecensa® capsules

Indication:

As monotherapy for the treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

http://www.scottishmedicines.org.uk/SMC Advice/Advice/1257 17 alectinib hydrochloride Alecensa/alectinib hydrochloride Alecensa Non Sub

Ibrutinib

Imbruvica® capsules

Indication:

In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

http://www.scottishmedicines.org.uk/SMC Advice/Advice/1258 17 ibrutinib Imbruvica/ibrutinib Imbruvica Non-submission

1258/17

Page 3 of 5

1188/16

Liraglutide

Saxenda® injection

Indication:

As an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of ≥ 30 kg/m² (obese), or ≥ 27 kg/m² to < 30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

http://www.scottishmedicines.org.uk/SMC Advice/Advice/1247 17 liraglutide Saxenda/liraglutide Saxenda Non Sub

Pertuzumab

Perjeta® infusion

Indication:

for use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

http://www.scottishmedicines.org.uk/files/advice/pertuzumab Perjeta 2nd Resub FINAL May 2017 for website.pdf

Safinamide

Xadago® tablets

Indication:

Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1259_17_safinamide_Xadago/safinamide_Xadago_Non-submission

Talimogene laherparepvec

injection

Imlygic®

Indication:

Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

http://www.scottishmedicines.org.uk/SMC_Advice/Advice/1248_17_talimogene_laherparepvec_Imlygic/talimogene_laherparepvec_Imlygic_Non_Sub

1248/17

1259/17

Panitumumab

Vectibix® infusion

Indication:

1st line metastatic colorectal cancer in combination with either FOLFOX or FOLFIRI:

- cetuximab for EGFR-expressing, RAS wild-type
- panitumumab for RAS wild-type in

ADTC Discussion points

The Committee noted that the NICE MTA supersedes SMC advice. This will be sent to RCAG for protocol development.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

https://www.nice.org.uk/guidance/ta439