ADTC(M) 16/04
Minutes: 40 - 54

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, 22 August 2016 at 2.00 p.m.

P R E S E N T

Dr J Gravil (in the Chair)

Mrs A Campbell	Dr K O'Neill
Mr R Foot	Dr J Simpson
Mrs Y Semple	Ms H Lindsay
Dr K McAllister	Dr A Bowman
Ms A Muir	Mrs L Hillan
Dr J Burns	Mrs A Thompson
Dr S Muir	

I N A T T E N D A N C E

Ms Heather Harrison.....Senior Prescribing
Mrs Mantej Chahal.....Prescribing Support Pharmacist
Ms Linda Collins.....Project Officer, ADTC Collaborative
Miss L Young.....Secretariat Officer

ACTION BY

40. 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.

She 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.

41. APOLOGIES AND WELCOME

Apologies for absence were intimated on behalf of Dr G Forrest, Dr A Seaton, Dr A Taylor, Dr R Hardman, Prof G McKay, Mrs J Watt, Mr Norman Lannigan, Dr A Crighton, Dr C Harrow and Mr A Crawford.

The Chair welcomed Mrs Mantej Chahal, Prescribing Support Pharmacist, who has taken over the role of Professional Secretary for the Polypharmacy Sub-Committee.

42. MINUTES

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on 13 June 2016 were approved as a correct record.

NOTED

43. MATTERS ARISING

Supply of Medicines Following Specialist Review or Clinic Appointments

Mrs Hillan informed members that the suggested changes submitted have been accepted. The GP Out of Hours Service has requested some amendments which are being made at the moment.

44. FORMULARY AND NEW DRUGS SUB-COMMITTEE

(1) **Report on SMC Product Assessments**

Dr Muir 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.

Accepted but not added

(a) alirocumab 75mg and 150mg solution for injection in pre-filled pen (Praluent®) [1147/16] *[Sanofi]**[Full Submission] [Indication: adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated]***

The SMC decision was "Accepted for restricted use within NHS Scotland"

The Committee noted that no outcome data is available yet. Local specialists have suggested this medicine should be used via lipid clinics only, however, a number of issues relating to implementation require to be resolved first.

The Committee agreed that this medicine should not be added to the Adult Formulary.

This medicine is not routinely available as implementation plans are being developed.

(b) vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®) [1158/16]*[Lundbeck Ltd]**[Full Submission] [Indication: the treatment of major depressive episodes in adults]***

The SMC decision was "Accepted for restricted use within NHS Scotland"

The Committee noted that clinical experts do not support adding this medicine to the Formulary as it offers no apparent benefits over existing options.

The Committee agreed that this medicine should not be added to the Adult Formulary.

This medicine is not routinely available because clinical experts don't wish to add to the Formulary at this time.

Major Changes

(c) brivaracetam 10mg, 25mg, 75mg, 100mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®)[1160/16]*[UCB Pharma Ltd]**[Full Submission] [Indication: Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy]***

The SMC decision was "Accepted for restricted use within NHS Scotland"

The Committee noted support from clinical experts to add this to the Formulary to offer another treatment option.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist initiation.

This medicine is available in line with national guidance.

(d) ibrutinib 140mg hard capsules (Imbruvica®) [1151/16] *[Janssen-Cilag Ltd.]**[Full Submission] [Indication: treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy]***

The SMC decision was "Accepted for restricted use within NHS Scotland"

The Committee noted that specialists are keen for this medicine to be available. It has been included in 2016/17 planning.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(e) ibrutinib 140mg hard capsule (Imbruvica®) [1150/16] *[Janssen-Cilag Ltd.]**[Full Submission][Indication: Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)]***

The SMC decision was "Accepted for use within NHS Scotland"

The Committee noted that specialists are keen for this medicine to be available. It has been included in 2016/17 planning.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(f) insulin degludec (Tresiba®) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen [856/13] *[Novo Nordisk Ltd.]* **[Resubmission]** ***[Indication: treatment of diabetes mellitus in adults]***

The SMC decision was "Accepted for use within NHS Scotland"

The Committee noted that this medicine has been accepted by SMC without restriction. The Committee noted that specialists feel this product would bring benefits. Potential safety issues were noted as this medicine is available in 100 and 200 unit per ml strengths. The Committee agreed that a prescribing note should be added to highlight that this medicine is available in 100 unit and 200 unit per ml.
The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with local guidance which advises on preferred options.

This medicine is available in line with local guidance.

(g) levofloxacin 240mg nebuliser solution (Quinsair®) [1162/16] *[Raptor Pharmaceuticals Europe B.V]**[Full Submission] [Indication: the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis]***

The SMC decision was "Accepted for restricted use within NHS Scotland"

The Committee noted support from clinicians to add this medicine to the Formulary.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist initiation.

This medicine is available in line with national guidance.

(h) nivolumab 40mg/4mL and 100mg/10mL vials of concentrate for solution for infusion (Opdivo®) [1144/16]*[Bristol-Myers Squibb Pharmaceuticals Ltd]* ***[Full Submission][Indication: Treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults]***

The SMC decision was "Accepted for use within NHS Scotland"

This is the first PD-1 inhibitor and immunotherapy medicine to be licensed for NSCLC. Mr Foot highlighted that the Early Access to Medicines Scheme (EAMS) for this medicine is now concluded.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

This medicine is available in line with regional guidance.

(i) nivolumab, 10mg/mL, concentrate for solution for infusion (Opdivo®) [1120/16] *[Bristol-Myers Squibb Pharmaceuticals Ltd]**[Resubmission] [Indication: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults]***

The SMC decision was "Accepted for restricted use within NHS Scotland"

This medicine has been included in 2016/17 planning.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

This medicine is available in line with regional guidance.

Minor Changes

(j) crizotinib, 200mg and 250mg hard capsule (Xalkori®) [1152/16] *[Pfizer Limited]**[Full Submission] [Indication: First-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)]***

The SMC decision was "Accepted for use within NHS Scotland"

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use in accordance with regional protocol (in development).

This medicine is available in line with regional guidance.

(k) emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film-coated tablets (Descovy®)

[1169/16] *[Gilead Sciences Ltd]**[Abbreviated Submission][Indication: in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1]***

The SMC decision was "Accepted for use within NHS Scotland"

The Committee noted clinicians feel this would be a useful addition. This medicine contains a different salt for tenofovir which appears to have reduced adverse side effects. Generic tenofovir is expected soon. The clinical teams are aware of this and it is under discussion.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to use by HIV specialists.

This medicine is available in line with national guidance.

(l) rilpivirine 25mg film-coated tablet (Edurant®) [1168/16] *[Janssen-Cilag Ltd]**[Abbreviated Submission][Indication: in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL)≤ 100,000 HIV-1 RNA copies/mL]*

The SMC decision was "Accepted for use within NHS Scotland"

The Committee noted the licence extension for 12-18 year olds.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to use by HIV specialists.

This medicine is available in line with national guidance.

(m) secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®)[1159/16] *[Novartis Pharmaceuticals]**[Full Submission][Indication: Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy]***

The SMC decision was "Accepted for use within NHS Scotland"

The Committee noted that clinicians welcome this new treatment for AS which targets a different pathway.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

This medicine is available in line with national guidance.

(n) secukinumab 150mg solution for injection in pre-filled pen and pre-filled syringe (Cosentyx®) [1167/16] *[Novartis Pharmaceuticals UK Limited][Full Submission][Indication: alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate]*

The SMC decision was "Accepted for restricted use within NHS Scotland"

The Committee noted that there is wide clinical support to add this medicine to the Formulary to offer another treatment option which targets a different pathway. The Committee noted that there is less information regarding long term safety than for anti-TNFs.

The Committee agreed that this medicine should be added to the Adult Formulary (Total Formulary) restricted to specialist use.

This medicine is available in line with national guidance.

Not recommended: the following medicines/indications were not included in Formulary as not recommended by SMC

(o) adalimumab (Humira®) Pre-filled Pen, Pre-filled Syringe and Vial [1173/16]*[AbbVie Limited]*

(p) afatinib (Giotrif ®) 20 mg/30 mg/40 mg/50 mg film-coated tablets [1174/16]*[Boehringer Ingelheim Limited]*

(q) azacitidine (Vidaza®) 25 mg/ml powder for suspension for injection [1175/16]*[Celgene Ltd]*

(r) elotuzumab (Empliciti ®) 300mg and 400mg powder for concentrate for solution for infusion [1183/16] *[Bristol Myers Squibb Pharmaceutical Limited]*

(s) human $alpha_1$-proteinase inhibitor 1,000mg powder and solvent for solution for infusion (Respreeza®) [1157/16] *[CSL Behring UK Limited][Indication: For maintenance treatment, to slow the progression of emphysema in adults with documented severe $alpha_1$-proteinase inhibitor (A1-PI) deficiency]*

(t) necitumumab (Portrazza®) 800mg concentrate for solution for infusion [1184/16] *[Eli Lilly and Company Limited]*

(u) ramucirumab (Cyramza®) 10 mg/ml concentrate for solution for infusion ®) [1176/16]*[Eli Lilly and Company Limited]*

Other Formulary Decisions

(v) NICE MTA 390: Canagliflozin, dapagliflozin, empagliflozin

Members noted the above MTA which supports the use of these medicines as monotherapy. The monotherapy indication will be added to the Formulary (Total Formulary) for each of these medicines, restricted to initiation by clinicians experienced in the management of diabetes.

Paediatric Formulary

(w) diamorphine hydrochloride 720 microgram/actuation and 1600 microgram/actuation nasal spray (Ayendi®) [1172/16] *[Wockhardt Uk Ltd]**[Abbreviated Submission][Indication: treatment of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray (Ayendi®) should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring]***

Deferred to the Paediatric D&T.

45. FORMULARY APPEAL: FORCEVAL® TABLETS

Mr Foot reported that two appeals were received for Forceval®, one for alcohol dependence and for patients who have undergone weight loss surgery.

Forceval® capsules (Alcohol Dependence)

Mr Foot summarised the points highlighted in the appeal. There are no hard outcome data in terms of evidence base.

DECIDED:

Following detailed discussion the Committee agreed that this medicine is not recommended for addition to the Formulary.

Forceval® capsules (Weight Loss Surgery)

Mr Foot highlighted that treatment would be lifelong for this patient group. Members noted that there is no hard outcome data in terms of evidence base.

DECIDED:

Following detailed discussion the Committee agreed that this medicine is not recommended for addition to the Formulary.

46. FORMULARY APPEAL: HYOSCINE BUTYLBROMIDE (BUSCOPAN®)

The above medicine has been suggested as an alternative first line treatment to be added to the preferred list to allow prescribers the choice of two agents for Irritable Bowel Syndrome. Mr Foot reported that there is no therapeutic advantage or disadvantage over current Formulary options however there is a lower acquisition cost. The Formulary and New Drugs Sub-Committee recommended adding this medicine to the preferred list and removing dicycloverine from the Formulary.

DECIDED:

Following discussion the Committee agreed to add this medicine to the preferred list on the Formulary and remove dicycloverine.

47. MEDICINES UTILIASATION SUB-COMMITTEE

Six Monthly Report

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

Dr O'Neill reported that 15 guidelines have been reviewed, 13 of which were approved.

He highlighted the Pharmacy Clinical Effectiveness Projects which are underway. Funding has now been received from the Scottish Government for a collaborative project with University of Strathclyde to evaluate the clinical effectiveness of Cancer Medicines, including patient reported outcomes. The CE team continue to supervise a number of band 6 pharmacy vocational projects.. Two proactive prescribing bulletins are being updated; the DOAC FAQ and Oral NSAIDs.

Dr O'Neil reported that an updated version of the GGC Medicines App will be available shortly. The Committee noted that the new desktop version was going live which now includes a new search functionality. Members are encouraged to provide feedback on the use of the desktop version and the search function to Mr Foot.

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

48. POLYPHARMACY SUB-COMMITTEE

Six Monthly Report

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

Mrs Harrison informed members that the main focus during 2015/16 was NHSGGC practices opting in to the Local Enhanced Service. Practices were asked to undertake face to face polypharmacy medication review with a maximum of 1.5% of the practice list. This was excluding ACP patient, nursing home patients and patients who had a polypharmacy review in the last year. From April 2015-March 2016 25,760 polypharmacy reviews were reported, against a target of 17,134.

Medicines Reconciliation

There were 5 elements to the care bundles which was detailed in the paper submitted. The care bundle

compliance at March 2016 was 92%. This has been stable for 12 months.

Members agreed it would be useful to see the work that has been carried out in care homes as this is a key piece of work. Mrs Chahal agreed to find out more information on the work that has been carried out and inform the Committee. Mrs Harrison reported that patient safety work is in progress. **Mrs Chahal**

Mrs Harrison reported that there is no polypharmacy LES planned for GP's in 2016/17. Work will continue with patient involvement groups, posters and campaigns for awareness. The Polypharmacy Sub-Committee has a new Chair, Dr Claire Langride. Mrs Harrison informed the Committee that discussions have taken place regarding dissolving or refreshing the Polypharmacy Sub-Committee.

The ADTC Committee agreed it would be helpful for the Sub-Committee to continue and provide updates on the work that is being carried out.

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

49. OTHER ADTC SUB-COMMITTEES

(a) Safer Use of Medicines Sub-Committee

Nothing specific to report.

(b) Prescribing Interface Sub-Committee

Nothing specific to report.

50. ADTC COLLABORATIVE

The Committee noted the July ADTC Collaborative newsletter.

Mr Foot reported that a medicines factsheet has launched. This will be available electronically. An ADTC Collaborative national conference is scheduled to take place on 24th November. Registration details will be circulated in due course.

A template policy outlining processes for declarations of interest was distributed to ADTC's earlier in the year. The template can be adopted or amended for local use if there is not a policy in place. Mr Foot reported that NHSGGC already have a template and a policy in place.

Mr Foot highlighted a recent change with nivolumab. This has been flagged to oncology therefore no direct action is required.

A Safer Use of Medicines Webex is due to take place on 24th August which members of the Committee can take part in. NHS Lothian is scheduled to provide a presentation on missed doses in hospital.

51. PRESCRIBING IN PRISONS

(a) Switch from the use of SF Methadone to standard Methadone in Prisons

Since the transfer of responsibility for the provision of primary and community health services from the Scottish Prison Service to the NHS, the NHS has continued the previous SPS policy of supply of SF Methadone for methadone opiate replacement therapies.

Consideration is now being given to switch to standard Methadone, which contains sugar, to align with what is received in the community. This would ensure continuity of care. The Committee discussed the side effects associated with sugar containing Methadone, in particular oral health. Mrs Thompson informed members that the reason for non-SF Methadone in the community was to prevent misuse. Members noted that the SF Methadone has a shorter shelf life.

Following discussion the Committee accepted the proposed recommendations. No changes are required to be made to the Formulary entry.

(b) Prescribing of Tramadol Products in Prison

The Committee noted that the Expert Advisory Group for Medicines in Prisons (EAGfM) has considered the impact of administering Tramadol products on Nurse resources in Prisons. The EAGfM has recommended that consideration should be given to using sustained release products in order to minimise the number of supervision episodes. Mr Foot reported that the levels of use are small.

Following discussion the Committee accepted the specific circumstances in this setting which supports variation from GGC Formulary.

52. PRESCRIBING MANAGEMENT GROUP REPORT

Ms Muir informed the Committee that the last meeting took place on 14th June. A prescribing overspend was noted. Discussions have taken place with community pharmacists regarding the fees for the supply of hep C medicines and a new fee structure has been agreed.

Ms Muir reported that information will be submitted to the Scottish Government regarding the new medicines fund. This work will be ongoing.

Cost reduction strategies were discussed for dressings and sundries.

The Committee noted the update provided.

53. ANY OTHER BUSINESS

Prescribing Management Group Primary Care: Clinical Guidelines Disclaimer Statement

Mrs Thompson informed members that the applicability of the clinical guideline disclaimer statement was discussed at the last meeting. The Committee confirmed that the statement was approved by ADTC and is included in the clinical guideline framework document.

Request for Change to Medicines in the GGC Formulary: Varenicline

Mr Foot tabled a request received from Public Health to move varenicline to the preferred list and amend the restriction to “restricted to use according to local protocol”. The request is based on a national piece of work on smoking cessation services. Members noted that the national varenicline PGD template now states that varenicline may be considered as a first line treatment along with NRT. Mr Foot reported that National Guidelines support the change. Ms Muir reported that Community Pharmacy are used to using varenicline, although it is not used often. Members noted that guidance needs to finally be agreed.

The Committee noted the information provided and agreed with change to Formulary status.

54. DATE OF NEXT MEETING

Monday, 10 October 2016 – Boardroom, JB Russell House, Gartnavel Royal Hospital