ADTC(M) 19/01
Minutes: 01 - 13

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 25th February 2019

P R E S E N T

Dr S Muir (in the Chair)

Mr R Foot	Mrs A Campbell
Ms G Caldwell	Mrs E McIvor
Dr R White	Mrs J Watt
Mrs L Hillan	Dr J Simpson
Mrs A Muir	Ms A Thomson
Mr A Crichton	Prof G McKay

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

Mrs L Russell Secretariat Manager

ACTION BY

01. 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.

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.

02. APOLOGIES AND WELCOME

Apologies for absence were noted on behalf of Dr B MacKinnon, Dr R Hardman, Dr A Fitchett, Dr C Harrow, Dr A Bowman, Mrs A Thompson, Ms F Thomson, Dr B White and D A MacLaren.

The Chair informed members that Dr B MacKinnon had tendered his resignation from the

Committee. The Chair thanked Dr MacKinnon for his contribution to the Committee over a number of years.

The Chair welcomed Ms Gail Caldwell, Director of Pharmacy and Ms Anne Thomson, Lead Clinical Pharmacist and new Chair of the Therapeutics Committee, to the Committee.

The Chair informed members that Ms Yvonne Clark has been appointed as Professional Secretary for the Committee.

03. MINUTES OF THE MEETING HELD 10th DECEMBER 2018

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on Monday 10th December 2018 were approved as an accurate record.

NOTED

04. MATTERS ARISING

No matters arising were noted.

NOTED

05. FORMULARY AND NEW DRUGS SUB COMMITTEE

1) Report on SMC Product Assessments

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.

Two declarations of interest were made.

See Appendix 1 for summarised decisions

06. FORMULARY & NEW DRUGS SUB-COMMITTEE – ANNUAL REPORT

The Committee noted the Formulary and New Drugs Sub-Committee Annual Report to inform ADTC of the work of the Sub-Committee.

The key business of the Formulary and New Drugs Sub-Committee is to support the implementation of advice on new medicines from SMC. The Committee noted the graph included in the report which compares SMC decisions from 2015-2018.

During 2018, advice on 27 medicines included the PACE step. Of the 27 medicines, 74% were cancer medicines. 15 were accepted and 5 were not recommended.

There is an increasing number of complex Patient Access Schemes (PAS) in place which offer an indication specific price. The Committee noted that this creates an additional

administrative burden for the service as data requires to be submitted.

One product was accepted by SMC but not added to the GG&C Formulary.

Mrs Campbell highlighted that the Single National Formulary Team intend to maintain engagement with stakeholders.

The Committee noted the activity and progress reported.

07. MEDICINES UTILISATION SUB-COMMITTEE – SIX MONTHLY REPORT

The Committee noted the Medicines Utilisation Sub-Committee Six Monthly Report to inform ADTC of the work of the Sub-Committee.

The key work of the Sub-Committee continues to focus on Guidelines/Protocols, Medicines Utilisation reports, Clinical Effectiveness Projects, GGC Therapeutics Handbook and Medicines Education. Dr White reported that 9 guidelines have been approved subject to minor changes and 6 of these are now posted within the GGC StaffNet Guideline Electronic Directory. In addition to these 9 new guidelines, the Sub-Committee have also received updates on guidelines which have been approved previously where implementation planning is still ongoing.

Dr Claire Harrow has resigned from the Committee therefore a replacement will be sought to represent secondary care.

Feedback on the DOAC booklets is welcomed from anyone who has looked at or used the booklets.

The Sub-Committee continue to receive updates on the progress of the GGC Medicines app and Therapeutics Handbook contents at each meeting. The GGC Medicines app continues to be updated. Guidelines are added to the Handbook using standard inclusion criteria.

Medicines Update Extra bulletins published within the last year include updates to:

- Drug QT Prolongation
- Parkinson's Disease in Acute Care
- DOAC prescribing in Patients with Non-Valvular AF and for the Treatment and Prevention of VTE

The Committee noted the good work carried out by the Sub-Committee and noted the developments.

08. OTHER ADTC SUB COMMITTEES

a) **Safer Use of Medicines Sub Committee**

Prof McKay informed the Committee that membership is good; there are one or two spaces which will be filled.
A proposal has been made for the Sub-Committee to increase meeting from 4 times to 6 times per year in order to keep momentum. Further discussions will take place regarding

this.

VRIII implementation remains a main item on the agenda. Other key topics are valproate and decision support for HEPMA.

The Sub-Committee will submit a 6 monthly report at the next meeting.

NOTED

b) **Therapeutics Sub Committee**

No specific update.

NOTED

c) **Prescribing Interface Sub-Committee**

No specific update.

The Sub-Committee will submit a 6 monthly report at the next meeting.

NOTED

d) **Communications Sub-Committee**

An on line survey to evaluate the Medicines Update blogs is underway.

NOTED

e) **Antimicrobial Sub-Committee**

No specific update.

NOTED

09. ADTC COLLABORATIVE UPDATE

The Committee noted the February newsletter which provides an update on the current work of the ADTC Collaborative.

Mr Foot highlighted that two medicines were available in January 2019 as part of the EAMS scheme. Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin for the treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with EGFR activating or ALK-positive tumour mutations after failure of appropriate targeted therapies and Dupilumab for the treatment of adolescent patients ≥12 to <18 years of age with severe atopic dermatitis who have responded inadequately to at least one systemic therapy or where the available systemic therapies are not recommended or are not tolerated.

A learning session for PACS Tier 2 and National Review Panel took place on 28th November 2018. There is an opportunity to submit any comments about the review process and the

NRP by 28th February 2019. NHS GGC are submitting a further response.

The newsletter includes an update on the National Palliative Care guidelines.

Feedback and learning has been shared from NHS Boards on their experience of implementing and driving benefits from HEPMA systems.

10. PMG UPDATE

Mrs Muir provided a brief update on the work of the Prescribing Management Group. Discussions are taking place around the impact of a no deal Brexit.

The group discussed the use of Freestyle Libre. A paper was produced which explained use in the previous year in line with guidance. This included information on how successful the MCN has been in managing the introduction of this device and the associated costs in line with budget.

11. NATIONAL PRISONER HEALTHCARE NETWORK EXPERT ADVISORY GROUP FOR MEDICINES

a) The Expert Advisory Group for Medicines (EAGfM) – Prescribing of Gabapentinoids for Neuropathic Pain for People in Prison

b) The Expert Advisory Group for Medicines (EAGfM) – Prescription and Administration of Buprenorphine in Prison Settings

The Committee noted 2 letters from the National Prisoner Healthcare Network on the prescribing of gabapentinoids and buprenorphine within the prison healthcare setting.

The Committee agreed it would be helpful to invite Mantej Chahal or Tracey Burton to the next meeting to provide a more detailed update on the use of these medicines in the prison healthcare setting. **Secretary**

12. AOCB

None.

13. DATE OF NEXT MEETING

Monday, 29th April 2019, 2pm, Boardroom, JB Russell House, Gartnavel Royal Hospital

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **25/02/2019**

Ertugliflozin

SMC2102

Steglatro® tablet

Indication:

In adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:
-As monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.
-In addition to other medicinal products for the treatment of diabetes.

ADTC Discussion points

This is a 4th SGLT2 inhibitor with same place in therapy as for other agents in class. The cost advantage is noted but a stronger evidence base exists for other agents in class in relation to cardiovascular outcomes.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to initiation by clinicians experienced in the managemern of diabetes for use as monotherapy and as add-on therapy. When used as monotherapy it is restricted to patients who would otherwise receive a dipeptidyl peptidase-4 inhibitor and in whom a sulphonylurea or pioglitazone is not appropriate.

Rivaroxaban

SMC2128

Xarelto® tablet

Indication:

Co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with coronary artery disease at high risk of ischaemic events

ADTC Discussion points

ADTC noted that use of rivaroxaban for this indication is expected to be limited due to the risk-benefit ratio. It was agreed that rivaroxaban for this population should only be initiated by a consultant. It was also noted that the restriction on use excludes patients with symptomatic peripheral artery disease. Further guidance could be provided by an appropriate Medicines Update blog for this medicine and indication.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to initiation by, or on the advice of a consultant only in patients with stable artery disease that do not require dual antiplatelet therapy.

Semaglutide

SMC2092

Ozempic® injection in pre-filled pen

Indication:

Treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise:
- As monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- In addition to other medicinal products for the treatment of diabetes.

ADTC Discussion points

This is the 5th GLP1 agonist: clinical specialists welcome this addition and indicate positive data from trials. SMC restriction reflects current place in therapy for this therapeutic class. A preferred option may emerge in time.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to initiation by clinicians experienced in the management of diabetes for use in addition to other oral anti-diabetic medicines, or as an add-on to basal insulin, as an alternative glucagon-like peptide-1 receptor agonist option.

Tofacitinib

SMC2122

Xeljanz® tablets

Indication:

Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.

ADTC Discussion points

An interim Formulary positioning was agreed by ADTC to support use in patients without other options whilst allowing the service to consider the most appropriate place in therapy within the existing clinical guidelines.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use only for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to conventional therapy and a biologic agent.

Tofacitinib

SMC2116

Xeljanz® tablet

Indication:

In combination with methotrexate for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

ADTC Discussion points

This offers a different mechanism of action and is the first oral biologic option for this indication. The local clinical guideline has been updated to incorporate this medicine.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use only in patients with psoriatic arthritis in accordance with local guidelines.

Dabrafenib

SMC2131

capsules Tafinlar®

Indication:

In combination with trametinib for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.

ADTC Discussion points

A regional protocol is in development, along with revision of the clinical management guideline to incorporate this treatment option.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol (in development)

Pertuzumab

SMC2120

Perjeta® infusion

Indication:

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

A regional protocol is in development, along with revision of the clinical management guideline to incorporate this treatment option.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

Tisagenlecleucel

SMC2129

Kymriah® infusion

Indication:

Treatment of paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse.

ADTC Discussion points

This medicine requires the development of a national service prior to implementation of routine use. It also requires the development of a supporting clinical protocol for use.

ADTC Decision:

Not routinely available as local implementation plans are being developed or ADTC is waiting for further advice from local clinical experts - Decision expected by:

Local restrictions on use:

Brivaracetam

SMC2113

Briviact® tablets, infusion, injection

Indication:

Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from 4 years to ≤15 years of age with epilepsy.

ADTC Discussion points

Paediatric D&T agreed to add this medicine to the Paediatric Formulary at their meeting on the 18th December 2018.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist initiation for adjunctive therapy in children from age 4 years with refractory epilepsy for the treatment of partial-onset seizures with or without secondary generalisation..

Ciclosporin

SMC2111

Verkazia® eye drops emulsion

Indication:

Treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.

ADTC Discussion points

Paediatric D&T agreed to add this medicine to the Paediatric Formulary at their meeting on the 18th December 2018

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to initiation by consultant ophthalmologists for the treatment of severe vernal keratoconjunctivitis (VKC) in children

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Dinutuximab beta

SMC2105

Qarziba infusion

Indication:

Treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease

ADTC Discussion points

Paediatric D&T agreed to add this medicine to the Paediatric Formulary at their meeting on the 18th December 2018.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use only in accordance with national protocols

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Fosaprepitant

SMC2108

Ivemend infusion

Indication:

prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in paediatric patients aged 6 months to 17 years.
Fosaprepitant is given as part of a combination therapy.

ADTC Discussion points

Paediatric D&T agreed to add this medicine to the Paediatric Formulary at their meeting on the 18th December 2018.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use only

Hydrocortisone

SMC2088

Alkindi® granules in capsules

Indication:

Replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to <18 years old).

ADTC Discussion points

Paediatric D&T agreed to add this medicine to the Paediatric Formulary at their meeting on the 18th December 2018.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

restricted to use in children up to age 6 years in whom hydrocortisone must otherwise be given by crushing or splitting tablets or by using specially-prepared solutions or buccal tablets in order to administer an age-appropriate dose.

Tiotropium

SMC2118

Spiriva® Respi solution for inhalation

Indication:

Add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.

ADTC Discussion points

Decision made by Paed D&T on 18/12/18.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Arsenic trioxide

SMC2025

Trisenox® infusion

Indication:

In combination with all-trans-retinoic acid (ATRA [tretinoin]) for the induction of remission, and consolidation in adult patients with newly diagnosed, low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤10 x 103/µl), characterised by the presence of the t(15;17) translocation and/or the presence of the Pro Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Axicabtagene ciloleucel

SMC2114

Yescarta® infusion

Indication:

Treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) and primary mediastinal large B cell lymphoma (PMBCL), after two or more lines of systemic therapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Cabozantinib

SMC2136

Cabometyx® tablets

Indication:

Advanced renal cell carcinoma (RCC) in treatment-naïve adults with intermediate or poor risk.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Cabozantinib

SMC2160

Cabometyx® tablets

Indication:

Monotherapy for the treatment of hepatocellular carcinoma in adults who have previously been treated with sorafenib.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Dexmedetomidine

SMC2161

Dexdor® infusion

Indication:

Sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Doravirine

SMC2162

Pifeltro® tablets

Indication:

In combination with other antiretroviral medicinal products, for the treatment of adults infected with human immunodeficiency virus 1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor class.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Doravirine, lamivudine, tenofovir

SMC2163

Delstrigo® tablet

Indication:

Treatment of adults infected with human immunodeficiency virus 1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor class, lamivudine, or tenofovir.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Pembrolizumab

SMC2127

Keytruda® infusion

Indication:

In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma (NSCLC) in adults whose tumours have no EGFR or ALK positive mutations.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Dupilumab

SMC2011

Dupixent® subcutaneous injection

Indication:

The treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

ADTC Discussion points

The introduction of this biologic was previously deferred to allow the development of a local protocol to govern use. This protocol has now been approved by Medicines Utilisation Subcommittee and therefore the addition of this medicine to Formulary can be completed. The local protocol give clear advice about previous treatment.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable in accordance with local guidelines.

Ixekizumab

SMC2097

Taltz® injection in pre-filled syringe

Indication:

Alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies.

ADTC Discussion points

A local clinical guideline for the use of biologic agents in psoriatic arthritis was developed to support the use of this, and other biologic medicines. Following approval of this guideline by Medicines Utilisation Subcommittee of ADTC, this medicine can now be added to Formulary.

ADTC Decision:

Routinely available in line with local or regional guidance
31/12/2018

Local restrictions on use:

Restricted to specialist use in accordance with local guidelines.
