ADTC(M) 19/04
Minutes: 46-59

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 12 August 2019

P R E S E N T

Mrs. Janice Watt (in the Chair)

Mr R Foot	Ms. B White
Dr. A Fitchett	Ms. J Torrens
Ms. A Thompson	Dr. A McLaren
Mrs. A Muir	Ms. A Campbell
Dr. R Hardman	Ms. Y Clark
Ms. A Thomson	Mrs. E McIvor
Dr. R White	

I N A TT E N D A N C E

Ms. J Torrens	Addictions Services Pharmacist
Ms. Y Al Din	Clinical Effectiveness Pharmacist
Mrs L Bulloch	Secretariat

ACTION BY

46. 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.

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.

47. APOLOGIES AND WELCOME

Apologies for absence were noted on behalf of Dr. S Muir, Ms. K McAllistair, Dr. A Taylor, Ms. Susan Donnelly, Ms. F Thompson, Mr. G McKay, Dr. J Simpson, Mrs. L Hillan, Dr. G Forrest, Mr. A Crighton, Mr. B McKinnon and

Ms. R Ford.

The Chair welcomed Ms. Jennifer Torrens, Addictions Services Pharmacist and Ms. Yasmin Al-Din, Clinical Effectiveness Pharmacist to the Committee.

48. MINUTES OF THE MEETING HELD 10th JUNE 2019

The minutes of the meeting of the Area Drugs and Therapeutics Committee held on Monday 10th June 2019 were approved as an accurate record.

NOTED

49. MATTERS ARISING

No matters arising were noted.

50. FORMULARY AND NEW DRUGS SUB COMMITTEE

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.

No declarations of interest were made.

See Appendix 1 for summarised decisions

51. UPDATE FROM RCAG PRESCRIBING ADVISORY GROUP

a) Summary of advice to NHS Board ADTC's July 2019

b) SACT Protocol Development and Review

c) Managed Entry of New Cancer Medicine or New Indications into Practice

Mrs. Campbell provided an update on protocols developed including an overview of the Standing Operating Procedure, Clinical Management guidelines, SACT protocols with guidance, WoSCAN templates and new medicine request forms.

52. FORMULARY APPEAL
Forceval® Capsules

Ms. Torrens provided an overview and a summary of important points highlighted in the appeal to use Forceval® Capsules for vitamin and mineral

deficiency associated with alcohol dependence. Ms. Torrens noted there was currently no equivalent multi-vitamin product on the NHSGGC Formulary. Ms. Torrens advised that the Alcohol and Drug Recovery Service were planning to use a screening tool to be developed by a Dietician, which would identify eligible patients and provide prescribing and review instructions to Medical Officers. Ms Torrens also advised the Committee that pilots of use on Forceval® had taken place in inpatients in NHSGGC

Questions were raised by the Committee regarding the place of Forceval® in the overall nutrition plan for these patients and whether patients were likely to adhere to treatment.

In conclusion the Committee required more understanding of the broader support to be provided to patients and where this would fit in the treatment plan for malnutrition. In summary, there was not strong support from the Committee in favour of using Forceval® over a 3 month period and members felt that there was insufficient evidence provided on the expected patient benefits. The Chair advised that the Committee would take into consideration Forceval® in the future once more evidence had been provided.

NOTED

53. MEDICINES UTILISATION SUB COMMITTEE

Dr. White gave an overview of the 6 monthly report from March - August 2019. The key areas of work focused on the Guidelines/Protocols, Medicine Utilisation Reports, Clinical Effectiveness projects, NHSGG&C Therapeutics Handbook and Medicine Education. Dr. White advised that 14 guidelines/protocols had been reviewed by the Sub Committee and 12 of the guidelines were approved with 8 currently posted on the NHSGG&C StaffNet Guideline Electronic Directory. Dr. White noted that a lot of work had been carried out with the implementation plans and guideline feedback with 4-5 guidelines being discussed at each meeting.

The Committee acknowledged the 6 monthly report and Mrs. Watt thanked Dr. White and the Committee for work completed on guidelines and feedback.

NOTED

54. IVACAFTOR
Five Year Outcomes in the West of Scotland Cystic Fibrosis Population

Ms. Al Din provided an overview of Ivacaftor, a Cystic Fibrosis (CF) Transmembrane Conductance Regulator (CFTR). Ms. Al Din advised that Ivacaftor was not recommended by the Scottish Medicine's Consortium for use within NHS Scotland. However, access to this medicine for patients with G551D mutation via a Patient Group Treatment Request had been available from 2013. Ms. Al Din explained the efficacy and safety of Ivacaftor for 9.5%

of the population of CF patients in NHSGGC with the G551D mutation. Ms. Al Din described that data had been created from 3 main trials, STRIVE: a randomised trial evaluating the effectiveness of Ivacaftor for patients of over 12 years or more for a period of 48 weeks. ENVISION: a randomised controlled trial evaluating effectiveness of Ivacaftor in children between 6-11 years of age for a period of 48 weeks. PERSIST: an open label extension study of participants in the STRIVE and ENVISON trial assessed on the safety and efficacy of Ivacaftor for an additional period of 96 weeks. Ms. Al Din provided an overview of the key parameters from the local data and results from tables on Page 4 from the paediatric and adult cohort with both showing an increased FEV1. Ms. Al Din highlighted there were limitations within the studies with the data being collected retrospectively and the limited details included in Clinical Portal.

Mr. Foot thanked Ms. Al Din for providing a fantastic piece of work which can provide additional data on exacerbation. The Committee agreed that the paper be more widely accessible to provide a better understanding. Ms. Al Din advised the Committee and the next steps would be to progress statistical analysis of the data and to work towards publication of the results. Mrs. Watt thanked Ms Al Din for providing a presentation of data to the Committee.

55. OTHER ADTC SUB COMMITTEES

a) Communications Sub Committee

No update

b) Medicines Utilisation Sub Committee

No specific update.

c) Safer Use of Medicine Sub-Committee

No update.

d) Therapeutics Sub-Committee

Ms. Thomson highlighted to Members that posters were being displayed in clinical areas in favour of treatment pathways for the product Prontosan. Ms. Thomson confirmed from the company B Bruan that the posters were a product promotion and not an official guideline.

NOTED

56. ADTC COLLABORATIVE UPDATE

Mr. Foot provided an update to Members from the ADTC Collaborative

Newsletter. Mr. Foot highlighted that the ADTC WebEx dates were available to all that were interested. Mr. Foot noted the New Ultra Orphan Pathway was fully operational. He provided an overview and advised that this new approach would allow new medicines for extremely rare conditions to be made available more rapidly to patients in Scotland.Some previously assessed medicines may now be eligible for the new pathway.

NOTED

57. PMG UPDATE

Ms. Muir noted two items of interest to Members. Ms. Muir provided an update to the ongoing work regarding off label use of bevacizumab for wet age related macular degeneration. Governance issues around off label use will be dealt with at a regional level.
Ms. Muir updated on the Clinical Management of Relapsing Remitting Multiple Sclerosis. in relation to the use of Ocrelizumab from the previous ADTC meeting. Ms. Muir advised further feedback was being sought from clinicians prior to consideration at PMG

Ms. Campbell

NOTED

58. AOCB

Ms. Muir raised a question with Members regarding Committee structures and agendas due to the Formulary and New Drugs Sub Committee disbanding. Members agreed to explore the membership status and agenda format of this Committee over the next 3 months to provide assurance to the Committee.

The Committee agreed that New Drugs item would be added to the agenda for members to discuss in detail and would be beneficial in discussion for future meetings.

NOTED

59. DATE OF NEXT MEETING

Monday, 7 October 2019, 2pm, Boardroom, JB Russell House, Gartnavel Royal Hospital

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **12/08/2019**

Buprenorphine

SMC2169

Buvidal® prolonged-release injection

Indication:

Treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.

ADTC Discussion points

ADTC noted that the introduction of this new formulation would require local implementation to ensure that mechanisms for supply and administration are appropriate, including consideration of controlled drug governance. The requirement for effective communication between the service and patient's GPs was noted. Local guidelines are to be updated by the service.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to use by GGC Alcohol and Drug Services in patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.

Empagliflozin plus Linagliptin

SMC 1236/17

Glyxambi® tablets

Indication:

in adults aged 18 years and older with type 2 diabetes mellitus:
- To improve glycaemic control when metformin and/or sulphonylurea (SU) and one of the monocomponents of Glyxambi® do not provide adequate glycaemic control
- When already being treated with the free combination of empagliflozin and linagliptin

ADTC Discussion points

ADTC noted that this combination is currently lower in cost than using the two same constituents separately. Relatively low use anticipated, as linagliptin typically used more in patients with decreasing renal function.

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 the treatment of type 2 diabetes when metformin and/or a sulfonylurea and one, or both of the two components do not provide adequate glycaemic control.

Inotersen

SMC2188

Tegsedi® injection

Indication:

Treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR).

ADTC Discussion points

This is the 2nd medicine for polyneuropathy in hATTR. ADTC noted the regular monitoring requirements and agreed that responsibility would remain with the specialist service. Also, it should be restricted in a similar manner to patisiran, including approval for prescribing from the National Amyloidosis Centre.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

The treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy is restricted to specialist use only on the advice of the National Amylodosis Centre.

Perampanel

SMC2172

Fycompa® oral suspension

Indication:

for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in adult and adolescent patients from 12 years of age with epilepsy.

ADTC Discussion points

Noted that this is an oral suspension of existing Formulary medicine. As the licence covers both children and adults, it will also need consdieration from a Paediatric Formulary perspective from the Paediatric D&T Committee.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist inittiation as use as a second-line adjunctive treatment in patients with refractory partial onset epilepsy who are unable to swallow perampanel tablets.

Arsenic trioxide

SMC2181

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

Referred to RCAG for the development of regionalal protocols for use.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocols.

Daratumumab

SMC2180

Darzalex® infusion

Indication:

In combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

ADTC Discussion points

Referred to RCAG for the development of regionalal protocols for use.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocols for use in combination with bortezomib and dexamethasone in adults with multiple myeloma who have received one prior therapy only.

Palbociclib

SMC2149

Ibrance® capsules

Indication:

Treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with fulvestrant in women who have received prior endocrine therapy.
In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

ADTC Discussion points

Referred to RCAG for the development of regionalal protocols for use.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocols.

Venetoclax

SMC2166

Venclyxto® tablets

Indication:

in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.

ADTC Discussion points

Referred to RCAG for the development of regionalal protocols for use.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocols

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Lenalidomide

SMC2217

Revlimid® capsules

Indication:

As combination therapy with bortezomib and dexamethasone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Perampanel

SMC2218

Fycompa® oral suspension

Indication:

The adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Pomalidomide

SMC2219

Imnovid® capsules

Indication:

In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Rucaparib

SMC2221

Rubraca®) tablets

Indication:

as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Darvadstrocel

SMC2115

Alofisel® injection

Indication:

treatment of complex perianal fistulas in adult patients with non-active / mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Encorafenib

SMC2145

Braftovi® capsules

Indication:

In combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Lumacaftor and Ivacaftor

SMC2182

Orkambi® tablets, granules

Indication:

Treatment of cystic fibrosis in patients aged 6 years and older (tablets) and aged 2 to 5 years (granules) who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

ADTC Discussion points

ADTC noted that access to this medicine had been via the Peer Approved Clinical System Tier 2 (PACS 2) process and this would continue to be the case.

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Tezacaftor and Ivacaftor

SMC2183

Symkevi tablets

Indication:

In a combination regimen with ivacaftor 150mg tablets for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T.

ADTC Discussion points

ADTC noted that access to this medicine had been via the Peer Approved Clinical System Tier 2 (PACS 2) process and this would continue to be the case.

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Nusinersen

SMC 1318/18

Spinraza® injection

Indication:

Treatment of type II and III (later onset) 5q spinal muscular atrophy (SMA)

ADTC Discussion points

ADTC noted that this was the first medicine to come through the new ultra-orphan pathway. The medicine is already routinely available to patients with type I SMC (via the Paediatric Formulary). Further service infrastructure is required for use in type II and III patient groups.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for the treatment of type II and III 5q spinal muscular atrophy (SMC). Formulary status will be reconsidered following the reassessment by SMC (expected July 2022).

(SMA type I is already accepted for use by SMC and is available in the Paediatric Formulary).
