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NHSGG&C(M) 20/03
Minutes: 30 - 45

NHS GREATER GLASGOW AND CLYDE

Minutes of the Meeting of the
Area Drugs and Therapeutics Committee
held via Microsoft Teams
on Monday 31st August 2020

PRESENT

Dr Scott Muir (in the Chair)

Mr Roy Foot	Mrs Elaine McIvor
Ms Yvonne Clark	Dr Gordon Forrest
Mrs Janice Watt	Dr Beth White
Dr Kay McAllister	Dr Roger Hardman
Mrs Audrey Thompson	Dr Craig Harrow
Dr Judith Simpson	Mrs Mairi-Anne MacLean

IN ATTENDANCE

Dr Catherine Bagot		Consultant Haematologist
Ms Colette Byrne		Lead Pharmacist, Medicines Governance
Mrs Louise Russell		Secretariat

			ACTION BY
31.	**CHAIRMAN'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.		
32.	**WELCOME AND APOLOGIES**		
	Apologies for absence were intimated on behalf of Mrs Alison Campbell, Mr Alastair Maclaren, Mrs Gail Caldwell, Dr Raymund White, Mr Alex Crighton, Prof Gerry McKay, Mrs Aileen Muir and Dr Fergus Maclean. **NOTED**		
33.	**MINUTES OF PREVIOUS MEETING: 24 FEBRUARY 2020**		
	The minutes of the meeting held on Monday 6th July 2020 were approved as an accurate record.		

	APPROVED		
34.	**MATTERS ARISING**		
	None. **NOTED**		
35.	**NEW MEDICINES FOR CONSIDERATION**		
	(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. No declarations of interest were made. *See Appendix 1 for summarised decisions*		
36.	**RCAG PRESCRIBING ADVISORY GROUP**		
	a) Summary of Advice July 2020 The Committee noted the paper provided for information. **b) COVID-19 Update** The Committee noted the paper provided for information. **NOTED**		
37.	**SAFER USE OF MEDICINES STRATEGY IN NHSGG&C**		
	Ms Colette Byrne, Lead Pharmacist, Medicines Governance, presented a paper proposing how NHSGG&C could make medicines use safer across hospital and community settings to improve the quality of care provided as described in the Board's Healthcare Quality Strategy. The report highlighted the following four key focus areas which had been identified to improve medicines safety across all settings in NHSGG&C; • Medication Systems & Practice • Patients & the Public • Healthcare Professionals • Medicines Governance Arrangements In response to a question in relation to the size of the team supporting implementation, Ms Byrne informed members that the Safer Use Of Medicines Subcommittee would monitor progress of the workplan, provide professional		

	advice and support resolution/escalation of barriers to progress. In addition, all sectors within acute services had a group, mental health had a group and primary care had their own structures in place. Following discussion, the Committee suggested inclusion of a governance structure would be helpful. Ms Byrne agreed to take the action forward. The Committee noted that the immediate focus would be on HEPMA. **DECISION:** Members of the Committee were happy to endorse the strategy. **APPROVED**		**Ms Byrne**
38.	**ADTC SUBCOMMITTEE UPDATES**		
	a. Prescribing Interface Sub-Committee Dr Hardman informed members that the next meeting of the subcommittee was scheduled for the following week. A six month report would be submitted to the next ADTC meeting. **b. Therapeutics Sub-Committee** Mrs McLean informed members that the subcommittee continued to meet virtually and compliance continued to be monitored. **c. Safer Use of Medicines Sub-Committee** No specific update. **d. Communications Sub-Committee** Mrs McIvor informed members that the subcommittee continued to circulate blogs and communications during the peak of the pandemic. Due to the large volume of work, a volunteer group was established to provide help with editing during this period. Mrs McIvor reported that 27 blogs were produced over a 10 week period and over 70 tweets sent out. A strategic meeting of the group would be held in November. Medicines Update continued to be promoted through Twitter, with new doctors and pharmacists and through post graduate coordinators. Mrs McIvor provided an update on the current membership. The subcommittee welcomed 2 new members, however, the subcommittee still remained short on medical representation. The Committee supported the request for medical representation and agreed to help raise awareness. **e. Antimicrobial Sub-Committee**		

	Dr White reported that communication would be going out on 14 September 2020 regarding new Empirical antibiotic guidance for Secondary Care and an updated IVOST guideline. Information would be disseminated regarding use of an online electronic form for ordering of protected antibiotics. The Committee acknowledged a push would be required in order to change practice. Dr White reported that vancomycin dosing guidance was likely to change, with a significant increase to the loading dose. **f. Medicines Utilisation Sub-Committee** No specific update. **NOTED**		
39.	**MEDICINE POLICY UPDATES**		
	The Committee noted the paper provided which summarised the changes made to the following 4 medicines policies; Non-Formulary Policy, PACS Ultra-Orphan Policy, IPTR Policy and IPTR Appeal Policy. Non-Formulary Policy The Committee noted the main changes were in relation to the Non-Formulary Policy. The policy had been revised and simplified to reflect wording used in related policies, for example PACS2 and IPTR. It is now a simple policy statement that non formulary prescribing should not be routine and existing national and local pathways should be followed. PACS Ultra-Orphan Policy A new review date was given to the PACS Ultra-Orphan Policy. IPTR Policy The Committee noted a minor refresh was made to the IPTR Policy. IPTR Appeal Policy The Committee noted minor updates were made to the IPTR Appeal Policy. The Committee noted that changes had been made to the communications section (section 14) regarding primary care. **DECIDED**: The Committee were content to endorse the updates. **APPROVED**		
40.	**SUPPLY OF MEDICINES FOR CYSTIC FIBROSIS (KATRIO)**		
	The Committee noted a letter received from the Scottish Government regarding a further revision to the pricing agreement between Vertex Pharmaceuticals and NHS National Procurement for Orkambi®, Symkevi® and Kalydeco®		

	The revised agreement was instigated in advance of the European Medicines Agency (EMA) granting a marketing authorisation for the triple therapy, Kaftrio©, which was expected in August 2020. The revised pricing agreement would; • Include Kaftrio® for the EMA licensed indications as well as a range of further genotypes (off-label) supported by national clinical guidance • Take account of any further licensed indications and/or licence extensions for all four products (Kalydeco®, Orkambi®, Symkevi® and Kaftrio®) • Include patients with rare mutations of the CFTR gene listed in the FDA label for the products but not currently included in the EMA licence • Ensure that pricing arrangements in Scotland are comparable to those agreed elsewhere in the UK. The change would come into effect on 1 September 2020 and the agreement would last for 4 years from August 2020. The Committee noted enthusiasm from the specialty. The Committee noted that use may increase however costs would be capped. The Committee noted that the new preparation would not be added to the Formulary at this time, instead it would be made available for patients. A formulary decision would be made in due course. **NOTED**		
41.	**ADTC COLLABORATIVE UPDATE**		
	The Committee noted the paper and newsletter provided for information. The last ADTCC Forum was held on 12 August 2020. Mr Foot reported that Lothian was the testing platform for the new Single National Formulary website. An update was provided at the meeting on how migration onto the new platform was progressing. It was noted that mapping medicines appeared to be challenging. Mr Foot agreed to provide an update on the ultra-orphan process at the next meeting. **NOTED**		
42.	**HEPMA PROGRESS UPDATE**		
	Mrs Watt provided an update on the progress with the implementation of HEPMA. The HEPMA Board had been formed and would be chaired by Dr Brian Digby. The Board had met 2 times to date and the design and build of HEPMA was progressing. A pilot would be carried out in November 2020 on the 7th floor at the Queen Elizabeth University Hospital. Mrs Watt informed the Committee that discussion regarding plans for full roll out were ongoing. Mrs Watt highlighted		

	that a key challenge would be integration of the medicines reconciliation functionality. A formal update would be provided at the next meeting. **NOTED**		
43.	**PMG UPDATE**		
	No specific update. **NOTED**		
44.	**ANY OTHER BUSINESS**		
	None. **NOTED**		
45.	**DATE AND TIME OF NEXT SCHEDULED MEETING**		
	Monday 26th October 2020, 2pm, Microsoft Teams		

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **31/08/2020**

Brolucizumab

SMC2272

Beovu® injection

Indication:

In adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).

ADTC Discussion points

Clinicians consider this to be a useful alternative if other current options are unsuitable. Will be incorporated into existing guidelines in due course.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with local protocol for the treatment of neovascular (wet) age-related macular degeneration (AMD).

Caplacizumab

SMC2266

Cablivi® injection

Indication:

Treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.

ADTC Discussion points

ADTC considered that a protocol for use would be required, but in light of small patient numbers, this should not delay addition to Formulary.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with local protocol.

Vedolizumab

SMC2276

Entyvio® pre-filled pen, pre-filled syringe

Indication:

Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.

ADTC Discussion points

Noted that this new formulation will covered by existing guidelines for vedolizumab

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with local guidelines.

Vedolizumab

SMC2277

Entyvio® pre-filled syring, pre-filled pen

Indication:

Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.

ADTC Discussion points

Noted that this new formulation will covered by existing guidelines for vedolizumab

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with local guidelines.

Andexanet alfa

SMC2273

Ondexxya® infusion

Indication:

For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

ADTC Discussion points

Guideline is in final stages of development, and includes the off-label use for reversal of patients on edoxaban, for which ADTC were supportive. Noted that this was accepted by SMC on an interim basis, and will be re-evaluated when it receives its full marketing authorisation.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to use only on the advice of a Consultant Haematologist for the reversal of anticoagulation due to life-threatening or uncontrolled bleeding in accordance with local protocol.

Polatuzumab vedotin

SMC2282

Polivy® infusion

Indication:

in combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant.

ADTC Discussion points

This medicine has been accepted by SMC on an interim basis and will be re-evaluated when it moves to a full marketing authorisation (MA). This has been referred to RCAG for development of a regional protocol and inclusion in the relevant clinical management guideline.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

Gilteritinib

SMC2252

Xospata® tablets

Indication:

as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation.

ADTC Discussion points

This has been referred to RCAG for development of a regional protocol and inclusion in the relevant clinical management guideline.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol

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Lorlatinib

SMC2239

Lorviqua® tablets

Indication:

Monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after:
- alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or
- crizotinib and at least one other ALK TKI

ADTC Discussion points

Following a change in view from RCAG, this is now to be added to Formulary and incorporated into regional protocols. This being a conditional licence, iwill be re-evaluated by SMC in due course.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

Neratinib

SMC2251

Nerlynx® tablets

Indication:

Extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.

ADTC Discussion points

This has been referred to RCAG for development of a regional protocol and inclusion in the relevant clinical management guideline.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

Pembrolizumab

SMC2247

Keytruda® infusion

Indication:

in combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults.

ADTC Discussion points

This has been referred to RCAG for development of a regional protocol and inclusion in the relevant clinical management guideline.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol and subject to a two-year clinical stopping rule.

Pembrolizumab

SMC2257

Keytruda® infusion

Indication:

as monotherapy or in combination with platinum and fluorouracil chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumours express programmed cell death ligand-1 (PD-L1) with a combined positive score (CPS)≥1.

ADTC Discussion points

This has been referred to RCAG for development of a regional protocol and inclusion in the relevant clinical management guideline.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol and subject to a two-year clinical stopping rule.

Pertuzumab

SMC2284

Perjeta® infusion

Indication:

for use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence.

ADTC Discussion points

This has been referred to RCAG for development of a regional protocol and inclusion in the relevant clinical management guideline.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol

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