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NHSGG&C(M) 20/04
Minutes: 46 - 58

NHS GREATER GLASGOW AND CLYDE

Minutes of the Meeting of the
Area Drugs and Therapeutics Committee
held via Microsoft Teams
on Monday 26th October 2020

PRESENT

Dr Scott Muir (in the Chair)

Mr Roy Foot	Mrs Elaine McIvor
Mrs Alison Campbell	Mr Alister Maclaren
Ms Yvonne Clark	Dr Gordon Forrest
Mrs Janice Watt	Dr Raymund White
Dr Kay McAllister	Dr Roger Hardman
Mrs Audrey Thompson	Dr Alex Crighton
Mrs Aileen Muir	Mrs Mairi-Anne MacLean
Dr Fergus MacLean	

IN ATTENDANCE

Mrs Louise Russell		Secretariat

			ACTION BY
46.	**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.		
47.	**WELCOME AND APOLOGIES**		
	Apologies for absence were intimated on behalf of Dr Judith Simpson, Mrs Gail Caldwell, Dr Craig Harrow, Prof G McKay and Dr Mohammed Khan. **NOTED**		
48.	**MINUTES OF PREVIOUS MEETING: 31 AUGUST 2020**		
	The minutes of the meeting held on Monday 31st August 2020 were approved as an accurate record.		

	APPROVED		
49.	**MATTERS ARISING**		
	None. **NOTED**		
50.	**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*		
51.	**ADTC SUBCOMMITTEE UPDATES**		
	a. Prescribing Interface Subcommittee – Six Monthly Report		
	The Committee noted the Prescribing Interface Subcommittee six monthly report to inform ADTC of the work of the Subcommittee from October 2019 to September 2020. The report highlighted that a change in workload due to COVID-19 had meant that the report covered a twelve month period. Dr Roger Hardman informed the Committee that personnel changes had been made following a number of resignations. Two new Doctors had joined the subcommittee. Following Linda Hillan's resignation, due to retirement, Kirsty Graham, Medicines Information Pharmacist, had joined the subcommittee to provide secretariat support. The subcommittee had considered a number of Shared Care Agreements over the last 12 months. The majority were existing SCP's which had been reviewed, updated and re-approved. The report highlighted the existing SCA's/SCP's (changed to SCA's when reviewed) which had been reviewed and new SCA's approved. Dr Hardman reported that LMC feedback was awaited for some SCA's. The growth hormone in children SCA, mentioned at the last meeting, was approved and posted to the GGC medicines Shared Care Agreement webpage. Dr Hardman highlighted that a number of medicines which secondary care wish to consider for shared care were currently on hold or under discussion as they required primary care monitoring. It was suggested that the new hubs may offer a way round monitoring issues in the future.		

	As agreed at the July ADTC meeting, Dr Hardman wrote to the relevant clinicians regarding guidance for transgender prescribing. Dr Hardman was informed that a national Gender Identity Clinic Network had produced a guideline which was revised in October 2018. The guideline included a section on monitoring and prescribing, which included a clear pathway. The pathway stipulated that the GP had responsibility for prescribing. The Committee acknowledged feedback that the pathway was detailed and the waiting lists for Sandyford were extensive, however the Committee agreed that as a national guideline was available, no local policy was required. The Committee acknowledged the 6 monthly report and noted the developments. NOTED		
	b. Therapeutics Subcommittee		
	Mrs Mairi-Anne MacLean informed the Committee that the Therapeutics subcommittee continued to meet virtually. Dr Ronnie Burns, GP, joined the Committee as a member. Mrs MacLean reported that an extension remained in place for the Formulary. Following discussion, the subcommittee was of the opinion that the name no longer reflected its purpose therefore a change of title to the subcommittee was proposed. Approval was sought to change the name to Non-Medicines Utilisation Subcommittee. The Committee approved the request. The Committee noted the update provided. **NOTED**		
	c. Safer Use of Medicines Subcommittee		
	Mr Alister MacLaren informed the Committee that the Safer Use of Medicines Strategy in NHSGGC was progressing to the next stage. Consultation was taking place with the Clinical Governance Groups for Acute, Primary Care and Mental Health. The next step would be to submit the strategy to the Board Clinical Governance Forum. The Committee noted the update provided. **NOTED**		

	d. Communications Subcommittee		
	Mrs McIvor informed the Committee that Dr Stefanie Lip, Locum CMT, had joined the subcommittee. Mrs McIvor reported that links had been shared from the medicines safety work that Dr Lip had been involved in. The Committee noted the update provided. **NOTED**		
	e. Antimicrobial Subcommittee		
	No specific update.		
	f. Medicines Utilisation Subcommittee		
	Dr White reported that the Medicines Utilisation subcommittee continued to meet virtually. At the last meeting 5 guidelines were reviewed and approved and a Formulary Appeal considered. The Committee noted the update provided. **NOTED**		
52.	**ADTC COLLABORATIVE UPDATE**		
	The Committee noted the newsletter provided for information. **NOTED**		
53.	**YELLOW CARD CENTRE SCOTLAND**		
	ANNUAL REPORT – APRIL 2019- MARCH 2020		
	The Committee noted the Yellow Card Centre Scotland Annual Report – April 2019-March 2020. Ms Yvonne Clark reported that there were no significant changes in the total reports compared to the previous year. The report highlighted that healthcare reporting was declining, which was mainly due to the decline in reporting from doctors across all sectors. Ms Clark reported that promotion of the yellow card scheme was taking place through education. In response to a question on whether the decline was due to other healthcare professionals prescribing, Ms Clark acknowledged that prescribing by nurses and pharmacists could have been a factor in the decline. The committee noted the report and the update provided.		

	NOTED		
54.	**HEPMA PROGRESS UPDATE**		
	Mrs Janice Watt provided an update on the progress with the implementation of HEPMA. Mrs Watt reported that an accelerated roll out programme continued to be pursued. This would help provide support with COVID-19. The focus continued to be on preparing for the pilot, which would commence on 16th November 2020 on the 7th floor at the Queen Elizabeth University Hospital. Mrs Watt reported that a vast amount of work was taking place and the system build continued. Mrs Watt reported that facilitators were in the process of being appointed. The HEPMA Programme Board continued to meet and advice sought from the ADTC Safer use of Medicines. Mrs Watt reported that a meeting was scheduled with pharmacy clinical governance colleagues and then a virtual meeting would take place with Safer use of Medicines. Mrs Watt informed members that full roll out was estimated to take place in February 2021. Further discussions regarding the order of the roll out within sites would take place. The Committee noted the update provided. **NOTED**		
55.	**GGC MEDICINES WEBSITE REFRESH 2020**		
	Mr Foot informed the Committee that a new GGC Medicines website was developed as the flashplayer for the current website was due to expire, therefore would be unable to upload to the website. Visually the new website was similar, with the search function marginally different. Mr Foot reported that re training would take place with staff that work at the back end of the website. Mr Foot reported that the feedback received to date on the look of the new website had been positive. The Committee noted the update provided. **NOTED**		
56.	**PMG UPDATE**		
	The last meeting was held on 22nd September 2020. This had been the first meeting post COVID outbreak.		

	Mrs Muir reported that the meeting mainly consisted of closing off previous agenda items. Mrs Muir highlighted in particular the CF pricing agreement which covered all patients and bevacizumab in ophthalmology. Prior to the COVID outbreak, work had been carried out in regards to the framework and supporting use of an unlicensed medicine. Mrs Muir reported that the framework had been approved by the Board Chief Executive, however there was no appetite for movement at the moment. Mrs Muir informed the Committee that an over spend in acute was discussed at the meeting however it transpired that income was reduced due to COVID. Mrs Muir reported that if this was covered by the Scottish Government then the over spend would be nil. The Committee noted the update provided. **NOTED**		
57.	**ANY OTHER BUSINESS**		
	(1) Significant Review Date Breaches - GGC Medicines Adult Therapeutics Handbook The Committee noted the additional paper submitted in order to discuss the options for guidelines within the GGC Medicines Adult Therapeutics Handbook (TH) that have significantly breached their review date. Mrs MacLean reported that a small cohort of guidelines had significantly breached their review date. Five guidelines had significantly breached, with 4 or more years since the last review despite reminders to lead reviewers. The report highlighted that while none of those five are known to have invalid content and all five have a breach banner advising the reader to exercise caution in the use of the guideline, it was felt that there must be a process to support governance of these significantly breached guidelines. Mrs MacLean informed the Committee that the issue had been raised with the Chiefs of Medicine. The Committee noted that the Clinical Governance Framework had no rules on unpublishing. Likewise, the Therapeutics Handbook Team were reluctant to have a strict unpublishing process, despite considerable discomfort around guidelines that have significantly breached their review date. The Committee were asked to consider developing an ultimate escalation plan The Committee acknowledged the requirement for breached guidelines to be dealt with however felt that breached guidelines should be reviewed on a case by case basis. The Committee were happy for the clinical team		

	to determine the level of risk and make an assessment. Guidelines where no decision could be made could then be escalated to the Committee. It was also suggested that guidelines may require two authors in the future. This was something that could be considered in the future. Mrs McLean agreed to link with Mrs McIvor in relation to the Safer Use of Medicines learning summaries following the meeting. Following discussion, Mrs Watt agreed to raise the item at the next Acute Clinical Governance Committee. **NOTED**		**Mrs McLean** **Mrs Watt**
	(2) Subcutaneous Infliximab and Formulary Mrs Campbell presented a paper in relation to subcutaneous infliximab. The paper highlighted that subcutaneous infliximab was now available however would not be assessed by SMC. The Committee noted that this formulation had a cost premium compared to the biosimilar infusions however was competitively priced. The Committee noted that clinical feedback indicated that there was interest in using subcutaneous infliximab; primarily to switch patients currently maintained on the infusion. Mrs Campbell highlighted that one of the benefits would be that the formulation could reduce footfall in acute care and attendance at day units. This would improve patient safety, particularly during the pandemic period. The Committee noted that uptake was expected to be modest in dermatology and rheumatology however up to 50% of gastroenterology patients on IV infliximab may switch to this preparation over the next 12 months. Mrs Campbell reported that financial approval had been given for this level of uptake for 2020/21 and would be included in the financial planning for 2021/22. The Committee noted that the preparation would not be the preferred anti TNF. In response to a question in relation to monitoring, Mrs Campbell confirmed that monitoring would remain with the specialist service. Following discussion, the Committee agreed to add the new formulation to the Formulary as a treatment option. **APPROVED**		
58.	**DATE AND TIME OF NEXT SCHEDULED MEETING**		

	Monday 14th December 2020, 2pm, Microsoft Teams		

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **26/10/2020**

Budesonide

SMC2158

Jorveza® orodispersible tablets

Indication:

Treatment of eosinophilic oesophagitis (EoE) in adults (older than 18 years of age).

ADTC Discussion points

Local clinical advice suggests that this will be used a maintenance treatment in most patients where it will replace off-label use of inhaled steroids.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

The treatment of eosinophilic oesophagitis (EoE) in adults is restricted to specialist initiation only in those patients unsuccessfully treated with proton pump inhibitors

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Fluocinolone acetonide

SMC2260

Iluvien® intravitreal implant

Indication:

Prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

ADTC Discussion points

ADTC noted that local experts consider this may be used in a small number of patients who are unable to be treated with systemic immunosuppression where it may displace Ozurdex implants, which are currently used off-label.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for the prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

Meropenem/vaborbactam

SMC2278

Vaborem® infusion

Indication:

for the treatment of the following infections in adults:
- Complicated urinary tract infection (cUTI), including pyelonephritis
- Complicated intra-abdominal infection (cIAI)
- Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

ADTC Discussion points

ADTC noted that this will be a Protected Antibiotic used under close scrutiny. Patient numbers are likely to be small and it will not be included in general infection management guidelines.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to use on the advice of a consultant microbiologist or infectious disease physician in adults with confirmed carbapenem-resistant Enterobacteriaceae (CRE)

Sodium zirconium cyclosilicate

SMC2288

Lokelma® oral suspension

Indication:

Treatment of hyperkalaemia in adult patients.

ADTC Discussion points

ADTC agreed that associated monitoring and review of this medicine would remain with the specialist service, with GPs undertaking the ongoing prescription.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist initiation in patients with hyperkalaemia (serum potassium >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level.

Semaglutide

SMC2287

Rybelsus® tablets

Indication:

for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise
-As monotherapy when metformin is considered inappropriate due to intolerance or contraindications
-In combination with other medicinal products for the treatment of diabetes.

ADTC Discussion points

ADTC noted this new formulation, which is the first oral GLP-1, which would be subject to the same formulary positioning as the injectable presentation.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Use in the treatment of type 2 diabetes mellitus (T2DM) is 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

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Human Corneal Epithelial Stem Cells

SMC2261

Holoclar® autologous stem cells

Indication:

Treatment of adult patients with moderate to severe limbal stem cell deficiency (defined by the presence of superficial corneal neovascularisation in at least two corneal quadrants, with central corneal involvement, and severely impaired visual acuity), unilateral or bilateral, due to physical or chemical ocular burns.

ADTC Discussion points

ADTC noted that this was accepted by SMC on an interim basis and will be subject to SMC reassessment after 3 year (expected to be September 2023). Formulary status will also be reconsidered at that point.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use for the treatment of patients with moderate to severe limbal stem cell deficiency, unilateral or bilateral, due to physical or chemical ocular burns.

Avelumab

SMC2248

Bavencio® infusion

Indication:

in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).

ADTC Discussion points

Referred to RCAG for development of protocol / inclusion in Clinical Management Guidelines

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Use in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC) is restricted to specialist use in accordance with regional protocol.

Carfilzomib

SMC2290

Kyprolis® infusion

Indication:

in combination with lenalidomide 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 development of protocol / inclusion in Clinical Management Guidelines

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 patients who have received only one prior therapy.

Daratumumab

SMC2301

Darzalex® subcutaneous injection

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 development of protocol / inclusion in Clinical Management Guidelines

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only in accordance with regional protocol.

Daratumumab

SMC2304

Darzalex® subcutaneous injection

Indication:

as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

ADTC Discussion points

Referred to RCAG for development of protocol / inclusion in Clinical Management Guidelines

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use as a fourth-line treatment option in accordance with regional protocol.

Ibrutinib

SMC2259

Imbruvica® tablets

Indication:

in combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia.

ADTC Discussion points

Referred to RCAG for development of protocol / inclusion in Clinical Management Guidelines

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Use in combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia is restricted to specialist use in accordance with regional protocol.

Lenalidomide

SMC2289

Revlimid® capsules

Indication:

as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT).

ADTC Discussion points

Referred to RCAG for development of protocol / inclusion in Clinical Management Guidelines

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Use as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT) is

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Lenalidomide

SMC2281

Revlimid® capsules

Indication:

In combination with rituximab (anti-CD20 antibody) for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 to 3a).

ADTC Discussion points

Referred to RCAG for development of protocol / inclusion in Clinical Management Guidelines

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with regional protocol.

Cannabidiol

SMC2262

Epidyolex® oral solution

Indication:

For use as adjunctive therapy of seizures associated with Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older.

ADTC Discussion points

It was noted that most patients who require this are already receiving it. Paediatric D&T will consider place in therapy from a Paediatric Formulary perspective. A protocol is in development to support the introduction of this medicine in the adult population

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:

30/04/2021

Local restrictions on use:

Cannabidiol

SMC2263

Epidyolex® oral solution

Indication:

For use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older.

ADTC Discussion points

It was noted that most patients who require this are already receiving it. Paediatric D&T will consider place in therapy from a Paediatric Formulary perspective. A protocol is in development to support the introduction of this medicine in the adult population.

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:

30/04/2021

Local restrictions on use:

Esketamine

SMC2258

Spravato® nasal spray

Indication:

In combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.

ADTC Discussion points

ADTC noted that Specialist Mental Health Services are developing plans for the safe delivery of this new treatment, which includes in the introduction of a new service to manage administration and observation. It is anticipated that this medicine may form part of a planned major depressive disorder pathway.

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:

30/04/2021

Local restrictions on use:

Fremanezumab

SMC2226

Ajovy® injection

Indication:

Prophylaxis of migraine in adults who have at least four migraine days per month.

ADTC Discussion points

ADTC agreed to defer addition to Formulary until a protocol for use was developed by the service. It was noted that this reflected the process followed for erenumab.

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:

10/08/2020

Local restrictions on use:

Siponimod

SMC2265

Mayzent® tablets

Indication:

Treatment of adult patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features of inflammatory activity.

ADTC Discussion points

First licensed therapy for SPMS and the clinical team are developing a 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:

30/04/2021

Local restrictions on use:

Cerliponase alfa

SMC2286

Brineura® infusion

Indication:

The treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.

ADTC Discussion points

ADTC Decision:

Local restrictions on use:

Voretigene neparvovec

SMC2228

Luxturna® injection

Indication:

Treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.

ADTC Discussion points

Noted that Scottish Government have now made this available via UO pathway. SMC will reassess in 3 years and formulary status will be reviewed at that point.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

The treatment of patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.