ADTC (M) 21/03
Minutes: 27 - 44

NHS GREATER GLASGOW AND CLYDE

Minutes of the Meeting of the Area Drugs & Therapeutics Committee held on Monday 9th August 2021, at 2pm via MS Teams

PRESENT

Mrs Janice Watt (in the Chair)

Mr Roy Foot	Mrs Mairi-Ann McLean
Mrs Alison Campbell	Dr Mohammed Khan
Dr Roger Hardman	Mrs Aileen Muir
Mr Alister Maclaren	Ms Judith Simpson
Mrs Laura Maguire	Mr Rob Puckett
Mrs Elaine McIvor	Dr Raymund White
Prof Gerry McKay	

IN ATTENDANCE

Mr Zack Barlow	..	Secretariat Officer (minutes)

			ACTION BY
27.	**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. 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. **NOTED**		
28.	**WELCOME AND APOLOGIES**		
	Apologies for absence were intimated on behalf of Dr Scott Muir, Ms Yvonne Clark, Dr Beth White, Ms Stefanie Lip, Dr Gordon Forrest, Dr Fergus MacLean, and Mrs Audrey Thompson. **NOTED**		

29.	**MINUTES OF THE MEETING HELD MONDAY 14th JUNE 2021**		
	The minutes of the meeting held on Monday 14th June 2021 were approved as an accurate record. **APPROVED**		
30.	**MATTERS ARISING**		
	There were no matters arising. **NOTED**		
31.	**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* **NOTED**		
32.	**BOTULINUM TOXIN FOR POST STROKE SPASTICITY**		
	Mr Foot presented the Committee with an SBAR regarding Botulinum Toxin for post-stroke lower-limb spasticity. It was advised that the Medicines Utilisation Subcommittee had recently reviewed the protocol and noted that it included reference to the use for post-stroke lower-limb spasticity, which due to non-submission to SMC was not recommended for use. The MU decision to not approve the guideline with the inclusion of this indication was supported. However it was noted that this type of scenario was considered to be problematic. It was agreed that Mr Foot would look to seek a national solution via the ADTC Collaborative. **NOTED**		**Mr Foot**
33.	**DIABETES MEDICINE INITIATION**		
	Mr Foot presented the Committee with an SBAR outlining current and proposed prescriber restrictions on who could initiate medicines for		

	diabetes. Mr Foot noted that the Committee had previous reviewed this area and had noted that there was inconsistency across the whole of the anti-diabetic sections within formulary. Mr Foot asked the ADTC to consider the recommendations noted within the report. The Committee discussed the options proposed and it was agreed that the following suggested recommendations would be supported: 1. Wording relating to those experienced in managing diabetes should be clarified further and be consistent and the following alternative wording: "Restricted to initiation by clinicians, either in primary care or the acute setting, experienced in the treatment of diabetes". In addition, this prescriber restriction would only be applied to GLP-1 agonists and insulins. 2. The specialist initiation symbol should be removed from all classes of antidiabetic medicines with the exception of GLP-1 agonist and Insulin Combination preparations, which remain restricted to initiation by Consultant Diabetologists . **APPROVED**		
34.	**DERMATOLOGY (EMOLLIENT AND BARRIER PREPARATIONS) FORMULARY SECTION REVIEW**		
	Mr Foot presented with Committee with a section from Formulary regarding Dermatology (Emollient and Barrier preparations) for review. Mr Foot advised that the prescribing team had facilitated a review of the Emollient and Barrier preparations with input from the specialist service. Due process was followed and the paper showed the summary of the changes suggested. It was noted that the main change was around bath and shower preparations. The Committee noted the importance of the new Formulary products being updated on ScriptSwitch as soon as possible. The Committee were content to endorse the changes made in Formulary. **APPROVED**		
35.	**MEDICINES UTILISATION SUBCOMMITTEE SIX MONTHLY REPORT**		
	Dr White presented the Medicines Utilisation Subcommittee Six Monthly Report to the Committee.		

	Dr White highlighted that the Subcommittee had reviewed 22 guidelines within the past 6 months of which 21 were approved, 13 of which had now been uploaded to the GGC Staffnet Guideline Electronic Directory. Work continued by the Clinical Effectiveness Team on a number of projects, further details were highlighted within the report. There were scoping opportunities for testing the use of HEPMA in CE/MUE work. NHSGGC continued to be involved in the development of a Regional Therapeutic Handbook, along with involvement from NHS Ayrshire and Arran and the Golden Jubilee National Hospital. The website was in testing which would be followed by app testing. The Chair thanked Mr White for the update and thanked the Subcommittee for their continued work. **NOTED**		
36.	**COMMUNICATIONS SUBCOMMITTEE SIX MONTHLY REPORT**		
	Mrs McIvor presented the Communications Subcommittee Six Monthly Report to the Committee. Mrs McIvor advised that the Committee continue to meet virtually every 4 weeks via Teams. 50 MU blogs had been published since the beginning of the year. Key blog themes continue to include patient safety, change in clinical practice and cost efficiencies. Social media accounts continued to gain more followers and links had been made with Corporate Communications and a programme of promotional activity had been developed. Work continued to remove historical content from the website. The Chair thanked Mrs McIvor for the update and thanked the Subcommittee for their continued work. **NOTED**		
37.	**PATIENT GROUP DIRECTION SIX MONTHLY REPORT**		
	The Committee noted the Patient Group Direction Six Monthly Report. The Chair noted in particular the work around the vaccines and the delegated responsibility that the Group has for approving the local use of the national patient group direction. Mr Foot questioned if PGD's should be approved for non-formulary medicines. It was suggested that if a PGD presented a clinical challenge then that specific PGD could be reviewed. **NOTED**		

38.	**OTHER ADTC SUBCOMMITTEE UPDATES**		
	No verbal reports were received from ADTC Sub Committees. **NOTED**		
39.	**SAFER USE OF SODIUM VALPROATE**		
	Mrs McLean presented a Safer Use of Sodium Valproate report to the Committee. Mrs McLean advised that the ADTCC were keen to learn from the experience of Boards in implementing this strengthened regulatory position for valproate and in the use of the valproate PPP and the annual risk acknowledge form. Mrs McLean asked the DTC to advise on any additional support that would support clinicians in the implementation of the prevent programme in all eligible patients. The Committee noted issues around the recording and reporting of the review within Neurology and Mental Health. The Chair recommended that this be raised with Acute Clinical Governance and Board Clinical Governance Forums. The Chair asked that the ADTC Safer Use of Medicines Group continue to monitor the situation. **NOTED**		
40.	**ADTC COLLABORATIVE UPDATE**		
	Mr Foot advised that there had been no recent meeting of the ADTC Collaborative. Mr Foot advised that NHSGGC comments regarding the Pharmacy First List had been put forward and considered. It was also noted that confidential primary care rebate schemes had been agreed. **NOTED**		
41.	**HEPMA PROGRESS UPDATE**		
	Mr Puckett presented a HEPMA progress update to the Committee. Mr Puckett advised that rollout to the QEUH had progressed well and to timescale. Ward 4C, renal transplant, had raised some issues around visibility of changes to medication and administrations for some drugs.		

	After discussion with the HEPMA Lead Pharmacist and SDPM, HEPMA was paused until the end of August. Other specialist areas, such as Bone Marrow Transplant, Neurosurgery and Maternity were challenging to implement, but with support from the facilitators and a responsive HEPMA pharmacy team, the team were able to maintain the service to these areas successfully. Generally, after 4-5 days the teams were comfortable using the system. Work was ongoing with some ED services to provide a virtual ward area where patients can be admitted on HEPMA before their actual inpatient admission, allowing prescribing to occur as it currently does without the need for paper to electronic transcription in more complex patients. The Clinical Reference Group continued to meet monthly where governance issues for HEPMA were discussed. The Committee noted that the work to integrate the IDL with HEPMA was ongoing. The rollout would continue across Gartnavel, the Beatson and GRI by the middle of September. Paediatric rollout would take place in April 2022. Following question regarding preparation for training, Mr Puckett advised that pharmacists would all receive 1:1 training The Committee noted the update provided. **NOTED**		
42.	**ANNUAL CYCLE OF BUSINESS**		
	The Committee noted the annual cycle of business. **NOTED**		
43.	**ANY OTHER BUSINESS**		
	Mrs Campbell raised that a NICE multi-technology appraisal on anti-TNF agents in moderate rheumatoid arthritis had been published which advised differently to the current NHS Scotland position. The Committee noted that, pending endorsement by HIS, rheumatoid arthritis guidelines may need to change locally. **NOTED**		
44.	**DATE AND TIME OF NEXT SCHEDULED MEETING:**		
	Monday 18th October, 2pm, via Microsoft Teams		

Appendix 1:NHS Greater Glasgow and Clyde New Medicines Decisions

Date of ADTC Decisions: **09/08/2021**

Avatrombopag

SMC2345

Doptelet® tablets

Indication:

Treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids or immunoglobulins).

ADTC Discussion points

This is the third thrombopoietin receptor agonist option (eltrombopag and romiplostim already in use).

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use in accordance with local protocol (in development) for use in patients with severe symptomatic immune thrombocytopenia (ITP) or with a high risk of bleeding who are refractory to other treatments.

Guselkumab

SMC2360

Tremfya® injection

Indication:

alone or in combination with methotrexate (MTX) 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

An additional treatment choice for PsA. This medicine is already formulary for psoriasis.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use, alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in patients:
1. who have had an inadequate response or who have been intolerant to two prior disease-modifying antirheumatic drug (DMARD) therapies.
2. whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and
3. in whom TNF inhibitors are contraindicated or not tolerated.

Inclisiran

SMC2358

Leqvio® injection

Indication:

Treatment for 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 who are 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.

ADTC Discussion points

ADTC request that the place in therapy be clearly noted in a clinical guideline or protocol prior to Formulary inclusion.

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:

01/02/2022

Local restrictions on use:

Ofatumumab

SMC2357

Kesimpta® pre-filled syringe/ pen

Indication:

Treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

ADTC Discussion points

Clinicians have agreed that this new mediicine will be used in the same position as ocrelizumab and will incorporate this into the clinical management guidelines. A prescribing note detailing the place in therapy will be added to Formulary entry until the guideline is updated.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use for the treatment of relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

Patiromer

SMC2381

Veltassa® oral suspension

Indication:

Hyperkalaemia in adults

ADTC Discussion points

This is now the second potassium binder accepted by SMC for this indication (the other being sodium zirconium cyclosilicate). Again, this is restricted to only a specific population of the licence, and is not routinely available for acute hyperkalaemia.

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.

Atezolizumab

SMC2349

Tecentriq® infusion

Indication:

In combination with bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

ADTC Discussion points

This will be referred to WoSPASG for protocol development

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)

Autologous anti-CD19-transduced CD3+ cells

SMC2351

Tecartus® infusion

Indication:

Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton’s tyrosine kinase (BTK) inhibitor.

ADTC Discussion points

This is ATMP with a conditional licence. Cases approved via national MDT.

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use only on the advice of the relevant National Multidiciplinary Team (MDT).

Avelumab

SMC2359

Bavencio® infusion

Indication:

Monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy.

ADTC Discussion points

This will be referred to RCAG for regional protocol development.

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).

Nivolumab

SMC2362

Opdivo® infusion

Indication:

Monotherapy for the treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy.

ADTC Discussion points

This will be referred to RCAG for regional protocol development.

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)

Olaparib

SMC

Lynparza® tablets

Indication:

Monotherapy maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

ADTC Discussion points

This will be referred to RCAG for regional protocol development.

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) in patients with BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Pertuzumab and trastuzumab

SMC2364

Phesgo® injection

Indication:

1) Early breast cancer (EBC) In combination with chemotherapy in:
- the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence
- the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence
2) Metastatic breast cancer (MBC)
In combination with 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

This will be referred to RCAG for regional protocol development.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

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

Delafloxacin

SMC2393

Quofenix® infusion, tablets

Indication:

Treatment of community-acquired pneumonia (CAP) in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Elotuzumab

SMC2407

Empliciti® infusion

Indication:

In combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Fostemsavir

SMC2389

Rukobia® MR tablets

Indication:

In combination with other antiretrovirals for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Imipenem/ cilastatin/ relabactam

SMC2390

Recarbrio® infusion

Indication:

Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Tafamidis

SMC2354

Vyndaqel® capsules

Indication:

Treatment of wild-type and hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

ADTC Discussion points

ADTC Decision:

Not routinely available as not recommended for use in NHSScotland

Local restrictions on use:

Fampridine

SMC2253

Fampyra® tablet

Indication:

Improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7).

ADTC Discussion points

This was deferred to allow for protocol and service development. The protocol for use is now approved and in place, so the formulary status is now able to be confirmed.

ADTC Decision:

Routinely available in line with local or regional guidance

Local restrictions on use:

Restricted to specialist use in accordance with local protocol

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Bempedoic acid

SMC2363

Nilemdo® tablets

Indication:

Adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
- In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (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 contra-indicated.

ADTC Discussion points

ADTC request that the place in therapy be clearly noted in a clinical guideline or protocol prior to Formulary inclusion.

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:

01/02/2022

Local restrictions on use:

Volanesorsen

SMC2299

Waylivra® injection

Indication:

As an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate.

ADTC Discussion points

The data collection plan has been agreed with Scottish Government and as such, this is now able to be added to Formulary until the SMC review (Nov 2023).

ADTC Decision:

Routinely available in line with national guidance

Local restrictions on use:

Restricted to specialist use.
