



**GMMMG Interface Prescribing
Subgroup**



Minutes

**13th August 2015, 1pm-3pm
Number One Riverside, HMR CCG
Smith Street, Rochdale**

Present:

Dr Richard Darling (RD) General Practitioner, Heywood, Middleton and Rochdale CCG (*Chair*)
Dr Jane Bradford (JB) General Practitioner, Bolton CCG
Hong Thoong (HT) Lead Pharmacist, Paediatric Medicine, CMFT
Robert Elsey (RE) Specialist Pharmacist, Pennine Acute Hospital Trust
Dr Heather Procter (HP) General Practitioner, Stockport CCG
Dr Simon Darvill (SD) Consultant Psychiatrist, Pennine Care NHS Foundation Trust
Jeanette Tilstone (JT) Medicines Management Lead, Bury CCG
Jason Farrow (JF) Medicines Management Pharmacist, Salford CCG Trust
Sarah Harris Lead Clinical Pharmacist, Pennine Care NHS Foundation Trust
Gary Masterman (GMa) Deputy Chief Pharmacist, Wigan Wroughtington and Leigh Foundation Trust
Anna Swift (AS) Medicines Management Pharmacist, Wigan CCG

Support:

Gavin Mankin (GM) Principal Pharmacist Medicines Management, RDTCC (*Professional Secretary*)
Andrew Martin (AM) Strategic Medicines Optimisation Pharmacist, Greater Manchester Shared Services (part of NW CSU)

In attendance:

Arifa Azmi Clinical Pharmacist, CAMHS, Pennine Care NHS Foundation Trust

Apologies received: Lesley Smith, Tom Leckie, Claire Foster, Robert Hirst, Robert Hallworth, Ben Woodhouse

Declarations of Interest

No declarations of interest relating to the agenda were raised.

1) Minutes of the meeting on 9th July 2015.

The minutes were accepted as a true and accurate record.

ACTION: RDTCC to publish as final.

2) Matters arising

2a) RAG List Recommendations from April meeting (Chapter 1 and 8) – awaiting GMMMG approval

These were approved by the GMMMG in July 2015. The RAG list on the website has now been updated.

2b) Shared care protocols for paediatric ADHD, Long acting antipsychotic injections, hydroxycarbamide, and growth hormone in adults

These were approved by the GMMMG in July 2015 and have now been added to the website. The shared care protocols for paediatric ADHD have now been amended slightly to highlight that *“prescribers should check local commissioning arrangements prior to implementing shared care as there may be variation in who is responsible for the physical health checks due to differences in local commissioning arrangements.”*

2c) RAG List Recommendations from May meeting

Comments on the following drugs were received and reviewed by the group:

- No comments received.

After discussion it was agreed that the following RAG rating be the final recommendation of the group:

| Product | Decision | | Notes on Decision |
|--|---|----------|--|
| | Status Assigned | Deferred | |
| 1) Requests deferred from previous meetings | | | |
| None | | | |
| 2) New Requests from New Therapies Subgroup and Formulary Subgroup | | | |
| Tiotropium for asthma | Green | | |
| Indacaterol/glycopyrronium (Ultibro®) inhaler | Green | | On DNP list and assumed if on DNP list then would be Red |
| Mysimba® (naltrexone/bupropion) for obesity | No status | | On DNP list |
| 3) RAG List Review – products on formulary currently with no RAG status | | | |
| Meformin in type 2 diabetes in paediatrics | Green (following specialist initiation) | | Use supported by BNFC |
| Amiodarone in paediatrics | | ✓ | To confirm current prescribing arrangements with local tertiary centres (Alder Hey) before making recommendation |
| 4) Changes to current RAG status | | | |
| Midodrine | Green (following specialist initiation) | | Change from Red then Green. Noted MHRA has now granted a product license for a UK product but not yet marketed. |
| Modafinil on paediatric RAG list | Red | | Change from Amber on paediatric RAG list. No change to adult RAG list |
| Olanzapine Pamoate depot injection | Red | | Change from Amber as needs 3 hour observation post-dose. |
| 5) No Change to Current RAG status | | | |
| None | | | |
| 6) Miscellaneous Decisions | | | |
| None | | | |

ACTION: GM to send final recommendation on RAG status of these drugs to the September 2015 meeting of GMMMG for approval.
GM to update RAG list and publish on website once approval received from GMMMG

2d) RAG List Recommendations from June meeting

Comments on the following drugs were received and reviewed by the group:

- Calcium resonium

After discussion it was agreed that the following RAG rating be the final recommendation of the group:

| Product | Decision | | Notes on Decision |
|--|---|----------|--|
| | Status Assigned | Deferred | |
| 1) Requests deferred from previous meetings | | | |
| Modafinil on paediatric RAG list | Red | | Change from Amber on paediatric RAG list. No change to adult RAG list |
| Amiodarone in paediatrics | | ✓ | To confirm current prescribing arrangements with Alder Hey |
| 2) New Requests from New Therapies Subgroup and Formulary Subgroup | | | |
| None | | | |
| 3) RAG List Review – products on formulary currently with no RAG status | | | |
| Fondaparinux | To have same RAG rating as LMWHs. | | |
| Bivalirudin | RED | | |
| Digoxin-specific antibody fragments | RED | | |
| Mifepristone | RED | | |
| Gemeprost | RED | | |
| Atosiban | RED | | |
| Carboprost | RED | | |
| Anti-D immunoglobulin | RED | | |
| Calcium resonium (oral) for hyperkalaemia | Green | | |
| 4) Changes to current RAG status | | | |
| Lanthanum for both dialysis and non-dialysis patients | GREEN (following specialist initiation) | | Change from GREEN (following specialist initiation) RAG status for use in non-dialysis patients but RED in dialysis patients. Confirmed with SRFT and NHSE that NHSE do not commission medicines associated with renal failure. |
| Sevelamer | GREEN (following specialist initiation) | | Change from GREEN (following specialist initiation) RAG status for use in non-dialysis patients but RED in dialysis patients. Confirmed with SRFT and NHSE that NHSE do not commission medicines |

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|---|-------|--|---|
| | | | associated with renal failure. |
| 5) No Change to Current RAG status | | | |
| None | | | |
| 6) Miscellaneous Decisions | | | |
| Ethinylestradiol for pubertal induction | Amber | | CMFT to develop an SCP. |
| Ciclosporin for paediatric nephrotic syndrome | Amber | | CMFT to develop an SCP. Confirmed with NHSE that they do not commission medicine aspect of paediatric nephrotic syndrome. |
| Hydroxycarbamide for myelofibrosis | Amber | | Same RAG status as Essential Thrombocythaemia or Polycythaemia, as Myelofibrosis is also a subcondition of Adult Myeloproliferative Disease . |

ACTION: GM to send final recommendation on RAG status of these drugs to the September 2015 meeting of GMMMG for approval.
GM to update RAG list and publish on website once approval received from GMMMG

2e) RAG List Recommendations from July meeting

These were circulated to Trusts and CCGs for comment with a deadline for comments of the 3rd September 2015. Any comments received will be reviewed by the group at the September 2015 meeting.

2f) Inclusion on Grey/DNP List Drugs on RAG List

Currently on hold pending the updated list/format of the Do Not Prescribe List from the formulary subgroup. The updated list was agreed at the August 2015 Formulary Subgroup and is now awaiting final GMMMG approval.

ACTION: GM to bring list of proposed entries for Grey/DNP List Drugs on RAG list to September 2015 meeting for discussion after the format and content has been agreed by the Formulary Subgroup.

2g) Amiodarone in paediatrics

Have now received confirmation from Alder Hey on the current regional RAG status of amiodarone in paediatrics. Within the Pan Mersey formulary amiodarone is classed as AMBER which simply means that this is not a drug which would be expected to be initiated by a GP in either adults or children. Once stabilised on therapy then many GPs will be happy to facilitate further supply from the community to prevent inconvenience to the patient- others will not be happy with this and will insist that prescribing is kept in house. This would be the equivalent of the GMMMG Green (following specialist initiation) RAG status.

For younger patients who will require the Amiodarone suspension 50mg/5ml (extemp preparation) then Alder Hey do have a specials scheme set up with certain CCGs in our area whereby GPs can request that Alder Hey supply the "special" paediatric formulation and the CCG is recharged . This is of benefit to the GPs in that they are charged standard tariff prices rather than the extremely high cost that might be incurred if supplied from a community based specials manufacturer.

The Pan Mersey Formulary Committee is planning to review all amber drugs and assign them to one of three amber categories:

Amber Recommended requires specialist assessment and recommendation to GP to prescribe in Primary Care.

Amber Initiated requires specialist initiation of prescribing. Prescribing to be continued by the specialist until stabilisation of the dose and the patient's condition is achieved and the patient has been reviewed.

Amber Patient Retained requires specialist initiation of prescribing. Prescribing to be continued by specialist until stabilisation of the dose and the patient's condition is achieved and the patient had been reviewed. Patient remains under the care of specialist (ie not discharged) as occasional specialist input may be required.

Amiodarone has not yet been through this review.

Within Greater Manchester CMFT emphasized the need to ensure consistency with the Alder Hey RAG rating as amiodarone in paediatrics is usually initiated by Alder Hey not CMFT. CMFT's preferred RAG status would be AMBER and they would happy to facilitate a share care protocol to support this.

After discussion the IPS agreed to assign an AMBER RAG status to the use of amiodarone in paediatrics as members felt it did not fit the criteria for a Green (following specialist initiation) drug as implied by the current Pan Mersey RAG status.

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| ACTION: AM to contact Trusts and CCGs with proposed RAG status. |
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3) Updated Terms of Reference including Voting and Appeals Process

At the August 2015 IPS meeting it was agreed to update the Terms of Reference of the group to include more robust procedures for the handling of appeals against RAG decisions that have been taken, and specifics on how such appeals will be discussed by the group.

The updated Terms of Reference were approved by the group with the suggested changes as follows:

- Membership – updated to reflect current membership with 8 x primary care reps and 9 x secondary care reps.
- Quoracy – updated to min 7 members present including 1 x GP and 2 x secondary care reps.
- Voting – agreed if decision is not unanomius it should be taken by majority vote and rather than Chair having casting vote that in the event if an equal split this would be communicated to GMMMG and they would be asked to take the decision.
- Appeals –
 - Grounds for appeal – agreed
 - No limits on timescale for appeals
 - Need for majority vote if required
 - Application to appeal will be heard at an IPS meeting to decide if grounds for appeal prior to be heard in full at a future IPS meeting with 30 minutes allocated to each appeal.
 - One meeting a quarter to include appeals as an agenda item.

The IPS also agreed to incorporate a lag period following GMMMG approval for implementation of those RAG recommendations plus Shared Care Protocols with major commissioning implications until these are resolved. The IPS did not feel a 90 day lag period was required for all RAG recommendations and new Shared Care Protocols, as not all these decisions would require a lag

period for implementation, and a wholesale lag period for all decision could result in unnecessary delays which impact on patient safety.

ACTION: GM to send amended Terms of Reference to September 2015 GMMMG for approval.
GM to publish on website once approved.

4) Interface Processes for Consultation on RAG List and Shared Care Protocols

Following discussions at the June 2015 GMMMG the IPS agreed to amend its process for consulting on changes to the RAG list and on new/amended shared care protocols. The updated processes were approved by the group.

The IPS also agreed the following:

- SCPs need to be checked against the BNF/SPC/NICE prior to being sent out for comment.
- To continue just with the current practice of sending draft RAG recommendations and SCPs to all Trusts/CCG Chief Pharmacists asking them to seek comments from within their organisation.
- Each chapter of RAG list and each SCP does not require a nominated primary care checker & secondary care checker but to continue with current practice of sending to all members of the IPS for comments.
- Need to include providers from outside Greater Manchester and non-NHS bodies in consultation process for those RAG decisions/SCPs that may have an impact on services they provide. This will be done by the Greater Manchester Shared Services (part of NW CSU).
- Mental Health SCPs may have an appendix detailing local variation of commissioning arrangements for each area BUT the core of the document to be the same e.g. what needs monitoring should not change between areas but who does it may?
- RAG lag list changes and SCPs approved by GMMMG to still be published on website within 3 working days of approval but to update the introductory statement to the RAG lists to say:
“RAG list entries with a NEW flag or UPDATED flag may be subject to a lag period to allow for commissioning approval and implementation by Trusts/CCGs. Please check with your individual Trust or CCG”

A similar statement to be added to the introduction on the SCP pages of the GMMMG website as follows:

“Shared Care Protocols with a NEW flag or UPDATED flag may be subject to a lag period to allow for commissioning approval and implementation by Trusts/CCGs. Please check with your individual Trust or CCG”

The IPS also discussed and approved a SHARED CARE PROTOCOL: APPROVAL CHECKLIST to be used in future when Shared Care Protocols are submitted to GMMMG for ratification. This incorporates scoring system as requested by GMMMG to indicate to commissioners and GMMMG the workload and commissioning implications for primary care plus secondary care associated with a particular shared care guideline.

ACTION: GM to send amended processes to September 2015 GMMMG for approval.
GM to send Shared Care Protocol: Approval Checklist to IPS members for comment prior to September 2015 GMMMG.
GM to send Shared Care Protocol: Approval Checklist to September 2015 GMMMG for approval.
GM to publish on website once approved.
AM to contact CCGs to confirm funding arrangements in their locality for SCPs.

5) Guidelines of defining RED/AMBER/GREEN Medicine Status – updated

The IPS reviewed and updated the GMMMG Guidelines for Defining RED/AMBER/GREEN Status. Changes made included:

- Review and clarification of RED indications
- Updated commissioning statement in relation to Specialist Commissioning & NHS England Commissioned Medicines
- The word “criteria” was changed to “guidance” throughout the document

ACTION: GM to send amended Guidelines of defining RED/AMBER/GREEN Medicine Status to September 2015 GMMMG for approval.

6) Clarification of 6mg dose of melatonin in paediatric melatonin SCP

IPS has been asked by Wrightington, Wigan and Leigh NHS Foundation Trust to clarify the reasoning behind the 6mg max dose of melatonin in the GMMMG Shared Care Protocol when the BNFC maximum dose is 10mg. The group noted that the decision was based on the NTS recommendation from Feb 2014: Use of Melatonin in sleep disorders in children and young people (Unlicensed Indication) which stated max dose as 6mg.

The IPS also noted that the MENDS trial on which the NTS recommendation was based included doses up to 12mg, with 30% of patients requiring doses <6mg.

The IPS felt it was unable to change the current dose recommendation in the shared care protocol without the NTS recommendation also being reviewed.

ACTION: GM to check with BNFC the basis for their max 10mg dose recommendation for melatonin in paediatrics.

Clinicians to be advised to seek consensus across Greater Manchester and to submit a request for NTS to re-consider their 6mg max dose recommendation.

7) Apraclonidine Eye Drops

The Formulary Subgroup has now reviewed the formulary status of apraclonidine eye drops as requested by the IPS and decided that no change to formulary is required. The FSG considered the comments from the specialists that this treatment is reserved for a group of patients who are complex to treat and is often their only option before surgery. They also discussed the concerns from the specialists regarding the impact that having to obtain this agent from the hospital rather than via primary care would have for this group of patients. The FSG agreed that the current listing in the formulary should remain i.e. ophthalmic consultant initiation for glaucoma.

After discussion the IPS agreed therefore needs Green (specialist initiation) status for glaucoma indication but RED for peri-operative use. The Green (specialist initiation) status for glaucoma would apply only to the Apraclonidine 0.5% eye drops noting that this an unlicensed indication.

ACTION: AM to contact Trusts and CCGs with proposed RAG status.

8) Drugs Requiring a Review of RAG status

- Amantadine for MS - currently no status – recommended be classified as Green (following specialist recommendation).
- Ezetimibe - currently no status – recommended be classified as GREEN.
- Pregabalin for neuropathic pain - currently no status – recommended be classified as GREEN.
- Acetazolamide for idiopathic intracranial hypertension - currently no status – recommended be classified as GREEN (following specialist recommendation).
- Naltrexone for opioid detoxification – currently no status – decision deferred pending confirmation of current prescribing arrangements/mechanism within each CCG. Noted that NICE recommend use under specialist supervision and monitoring.

ACTION: AM to contact Trusts and CCGs with proposed RAG status.

AM to contact providers of drug misuse services to find out current prescribing arrangements/mechanism for naltrexone for opioid detoxification in each of the areas where they are commissioned provider i.e. does the provider issue the prescription or do they ask the GP to issue the prescription.

9) New Drugs from NTS and Formulary Subgroup requiring a RAG status

- Simbrinza® (Brinzolamide/Brimonidine) eye drops - recommended be classified as GREEN.
- Secukinumab for moderate to severe plaque psoriasis – recommended be classified as RED.
- Apremilast for moderate to severe chronic plaque psoriasis and psoriatic arthritis – recommended be classified as RED.

ACTION: AM to contact Trusts and CCGs with proposed RAG status.

10) Shared Care Protocols for Approval

The following existing SCP had been put into the GMMMG format and updated following comments received from the original authors:

- Mercaptopurine and Azathioprine for Inflammatory bowel disease
- Azathioprine for the treatment of chronic inflammatory bowel disease (unlicensed use) in paediatric patients
- SSRIs in children and adolescents for OCD & BDD
- SSRIs in children and adolescents for depression
- SSRIs in children and adolescents for anxiety
- Antipsychotics for schizophrenia in children & adolescents
- Antipsychotics for OCD in children & adolescents
- Antipsychotics for Bipolar in children & adolescents

The group agreed that these could now be sent out to CCGs and Trusts for further comments with a deadline of 9th September 2015 prior to going to September 2015 GMMMG for approval subject to only minor comments being received.

With regard to the SSRI SCPs and Antipsychotic SCPs in paediatrics the group discussed and noted that changes recommended by NICE with regard to responsibility for monitoring physical health and the effects of antipsychotic medication. The group noted that how these checks are carried out still needs to be resolved with commissioners and may vary between CCGs but it was not the remit of the IPS to resolve.

ACTION: AM to send to CCGs and Trusts for further feedback with deadline of 9th September 2015. If no major changes required then to go to September 2015 GMMMG for final approval.

11) Nalmefene Shared Care Protocol – 2nd draft

Item deferred until September 2015 meeting of the IPS due to time constraints.

12) Progress with GMMMG versions of SCPs as of July 2015

A spreadsheet detailing progress on developing GMMMG versions of Share Care Protocols for all the AMBER drugs was shared with the group for information.

Pennine Care agreed to produce a draft of a paediatric lithium SCP for discussion at September 2015 IPS meeting.

13) NOAC Alert Card

This alert card produced by the Northern England Strategic Clinical Network has come through the MSO network and CCGs are keen to adopt it locally.

IPS have been asked to comment on it from a safety view point and make recommendation to GMMMG for sign off.

The IPS felt that the alert cards produced by each NOAC manufacturer were adequate and available free of charge (unlike the regional NOAC alert card). Also they group questioned if patient's would actually use and carry the regional NOAC alert card in addition to the manufacturer card, and/or could be confused by having two versions of the alert card.

ACTION: GM to send recommendation to Sept 2015 GMMMG not to adopt the Northern England Strategic Clinical Network NOAC alert card within Greater Manchester.

14) Monitoring of Drugs in Primary Care

GMMMG suggested at their July meeting having a monitoring document for all amber drugs so that practices could see at a glance what drugs need monitoring so they can set up recalls on their practice systems. An example of such a document from UKMi was provided to the IPS.

The IPS felt a separate document was not required as would onerous to maintain and monitoring requirements for each AMBER drug are specified in the appropriate Share Care Protocol. Instead the IPS agreed that a link to the UMKi document could be added to the GMMMG website.

ACTION: GM to send recommendation to Sept 2015 GMMMG that a link to the UMKi Drug Monitoring document could be added to the GMMMG website.

15) Shared Care Protocols – drafts to go out to CCGs/Trusts for comment

Due to time constraints no discussion took place. But was agreed to circulate final drafts of each of the following shared care protocols to Trust/CCGs via email for comment. These comments will then be collated and the final draft updated as necessary for approval at October 2015 IPS meeting

- Ethinylestradiol for pubertal induction
- Ciclosporin for paediatric nephrotic syndrome
- Riluzole

ACTION: AM to circulate drafts of these Shared Care Protocols to Trust/CCGs via email for comment.

16) Declarations of Interest 2015/16 – now due

Members were reminded to submit completed annual Declaration of Interest Forms for year 2014/15 if not already done so as per GMMMG policy.

17) Updates from Other Groups

Due to time constraints no verbal update was given but update included in the minutes for information.

New Therapies Subgroup

At their July 2015 meeting the NTS reviewed Vortioxetine, Ivermectin, Xultrophy® and the local COPD pathway. Their next meeting is in September 2015.

Formulary Subgroup

The group continues to review the formulary content of Chapter 4. Work continues on reviewing the DNP /Grey list

GMMMG

The August 2015 meeting of GMMMG has been cancelled.

18) AOB

Colobreathe Inhaler and Tobi Podhaler

The group has been asked to consider assigning a RAG status for Colobreathe Inhaler and Tobi Podhaler for cystic fibrosis as they are not currently on the RAG list.

The group noted that both these drugs as PBR excluded and commissioned by NHS England with prescribing currently being repatriated to secondary care.

NICE TA276 approved the use of Colobreathe subject to be available via a Patient Access Scheme.

Prescribing data shows there is currently no prescribing of the Colobreathe inhaler within primary care in Greater Manchester.

The group was minded to recommend that Colobreathe Inhaler and Tobi Podhaler be added to the RAG list as RED drugs but this was subject to arrangements for repatriation and how the Patient Access Scheme being confirmed with the current commissioned provider.

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| ACTION: AM to confirm status of repatriation and current prescribing arrangements via PAS with UHSM. |
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Date of Next Meeting: 10th September 2015, 1pm-3pm Dawes Family Practice, 83 Spotland Road, Rochdale OL16 1XU