GMMMG Interface Prescribing Subgroup

Minutes

14th May 2015, 1pm-3pm

Number One Riverside, HMR CCG
Smith Street, Rochdale

Present:

Dr Richard Darling (RD) General Practitioner, Heywood, Middleton and Rochdale CCG *(Chair)*

Claire Foster (CF) Medicines Management pharmacist, Central Manchester CCG

Robert Hallworth (RH) Specialist Cancer Pharmacist, North of England Area Team, NHS England

Robert Elsey (RE) Specialist Pharmacist, Pennine Acute Hospital Trust

Dr Heather Procter (HP) General Practitioner, Stockport CCG

Gary Masterman (GMa) Deputy Chief Pharmacist, Wigan Wrightington and Leigh Foundation Trust

Dr Tom Leckie (TL) Consultant, Pennine Acute Hospital Trust

Ben Woodhouse (BW) Medicines Management Lead, Bolton CCG

Dr Jane Bradford (JB) General Practitioner, Bolton CCG

Robert Hirst (RH) Senior Pharmacist, Tameside Foundation Trust

Dr Simon Darvill (SD) Consultant Psychiatrist, Pennine Care NHS Foundation Trust

Support:

Gavin Mankin (GM) Principal Pharmacist Medicines Management, RDTC *(Professional Secretary)*

Andrew Martin (AM) Strategic Medicines Optimisation Pharmacist, NW CSU

In attendance:

Sarah Harris Deputy Chief Pharmacist, Pennine Care NHS Foundation Trust

Apologies received: Anna Swift, Robert Hallworth, David OReilly, Lesley Smith, Jeanette Tilstone, Jason Farrow, and Hong Thoong

Declarations of Interest
No declarations of interest relating to the agenda were raised.

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

The minutes were accepted as a true and accurate record.

ACTION: RDTC to publish as final.

2) Matters arising

2a) RAG List Recommendations LMWH – now GMMMG approval

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

An additional supporting document in a similar format to the East Lancs LMWH document detailing each indication for LMWH and its RAG status has been added to password protected section of the GMMMG website.

2b) RAG List Recommendations from February meeting – now GMMMG approved

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

2c) RAG List Recommendations from March meeting – awaiting GMMMG approval

These were circulated to Trusts and CCGs for comment.

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

- Dornase alfa – suggest to remain Amber until repatriation to secondary care is complete.
- Dapsone – ensure RAG list specifies indication
- Nalmefene – confirmed AMBER as should only be prescribed by GP if patient is receiving psychosocial support.

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			
Drugs for alcohol dependence (nalmefene, acamprosate and disulfiram)	Acamprosate & Disulfiram – remain AMBER but note that local commissioning arrangements may vary. Naltrexone – currently RED - no change recommended. Noted that has higher level of risk and monitoring requirements than acamprosate or disulfiram. Nalmefene for alcohol dependence – currently no status – recommended be classified as AMBER.		
2) New Requests from New Therapies Subgroup and Formulary Subgroup			
None			
3) RAG List Review – Chapter 3,12 & 13 (products on formulary currently with no RAG status)			
Bee & wasp allergen (Pharmalgen®)	Red		Should only be prescribed and administered by specialists.
Pirfenidone	Red		Should only be prescribed and administered by specialists.
C1-esterase inhibitor	Red		Should only be prescribed and administered by specialists.
Conestat alfa	Red		Should only be prescribed and administered by specialists.

Icatibant	Red		Should only be prescribed and administered by specialists.
Ivacaftor	Red		Should only be prescribed and administered by specialists.
Grass pollen extract	No status required		On DNP list
Poractant alfa (Curosurf®)	Red		Should only be prescribed and administered by specialists.
Mannitol inhaler	Red		Should only be prescribed and administered by specialists.
Salbutamol injection	Red		Should only be prescribed and administered by specialists.
Aminophylline injection	Red		Should only be prescribed and administered by specialists.
Azathioprine for interstitial lung disease	Red		Should only be prescribed and administered by specialists. Use not recommended by NICE.
Tacrolimus ointment	Green (following specialist advice)		For initiation by specialist only on formulary.
Pimecrolimus	Green (following specialist advice)		For initiation by specialist only on formulary.
Dithranol (licensed preps)	Green (following specialist advice)		
Dithranol (unlicensed preps)	Red		Unlicensed
Ustekinumab	Red		Should only be prescribed and administered by specialists.
Dapsone for leprosy and dermatitis herpetiformis	Green (following specialist advice)		
DMARDs when used in dermatology (ciclosporin, oral methotrexate, azathioprine, mycophenolate).	Amber		As per RAG status for all other indications for DMARDs
4) Changes to current RAG status - Chapter 3,12 & 13			
None			
5) No changes to current RAG status - Chapter 3,12 & 13			
Dornase alfa	Amber		To remain amber until repatriation to secondary care complete.
Omalizumab	Red		No change
Acitretin	Red		No change
Alitretinoin	Red		No change
Botulinum toxin	Red		No change
Isotretinoin (oral)	Red		No change
6) Miscellaneous Decisions			
None			

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

2d) RAG List Recommendations from April meeting

These were circulated to Trusts and CCGs for comment with a deadline for comments of the 7th June 2015. Any comments received will be reviewed by the group at the June 2015 meeting.

2e) Ethinylestradiol for Pubertal Induction

Item deferred until the June meeting of the IPS due to time constraints and as CMFT representative not present.

2f) Ciclosporin for use in Childhood Nephrotic Syndrome

Item deferred until the June meeting of the IPS due to time constraints and as CMFT representative not present.

3) RAG List Review

The IPS has now completed the full review of each chapter of the RAG list since the IPS was re-established in July 2014. In future the IPS will only review the RAG status of a drug if new evidence supporting a change becomes available OR if it receives a request from the GMMMG, New Therapies Sub-group, the Formulary Sub-group or from Trusts/CCGs.

4) Drugs Requiring a Review of RAG status

Midodrine

The group discussed the RAG status for Midodrine which is currently on RAG list as RED then Green once stabilised. The group agreed that it should be given a Green (following specialist initiation) RAG status. It was noted that the MHRA granted a marketing authorisation to a UK product in March 2015 with an SPC and patient information leaflet available on their website, but this product has yet to reach the market.

Modafinil on Paediatric RAG List

The group agreed to recommend that use of modafinil in paediatrics should be classed as RED not AMBER. This is because it is not licensed for use in those under 18yrs old in line with MHRA Drug Safety Update from March 2011.

Metformin in Paediatrics

A request has been received to review the RAG status of metformin in paediatrics and include it within the paediatric RAG list. The group agreed to recommend that it should be given a Green (following specialist initiation) RAG status. It was noted that is included in the BNFC and that the monitoring / side-effect profile does not differ to use in adults.

Amiodarone in Paediatrics

A request has been received to review the RAG status of amiodarone in paediatrics and include it within the paediatric RAG list. It was agreed to defer a decision until the next meeting of the IPS so that the current prescribing arrangements for use of amiodarone in paediatrics by tertiary centres within the NW region could be confirmed.

ACTION:	**AM to contact Trusts and CCGs with proposed RAG status.** **GM to confirm with CMFT current prescribing arrangements for use of modafinil in paediatrics.** **GM to confirm current prescribing arrangements for use of amiodarone in paediatrics with tertiary centres within the NW region.**

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

a) Tiotropium for asthma – currently Green for COPD - recommended be classed as Green for asthma.

b) Ultibro® (indaceterol/glycopyrronium) inhaler – recommended be classed as Green.

c) Mysimba® (naltrexone/bupropion) – recommended no status required as not recommended for use by NTS and is being considered for inclusion of the GMMMG DNP list.

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

6) Progress with GMMMG versions of SCPs

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

In summary:

a) Chapter 10

The update of the shared care protocols for the drugs in Chapter 10 remains on hold pending updated BSR guidance on monitoring of DMARDs.

b) Chapter 9 - Hydroxycarbamide

Currently out for comment with CCGs/Trusts until 4th June 2015.

c) Chapter 5 – colistimethate for non-CF patients

A first draft of this SCP has been prepared and sent to the original author at SRFT for comment and CMFT have also asked to be involved in the development process. There are some issues around supply of consumables that need to be resolved before the 1st draft is ready for external comment.

d) Chapter 4 SCP Review

- ADHD drugs – 2nd draft has been sent to Pennine Care and CMFT (the original authors) for comment. Received comments from Pennine Care 5.2.15 and from CMFT on MPH on 16.4.15.
- Long acting injections – currently out for comment with GMW and MHSC until 30.4.15. Comments now all received and final draft now in preparation.
- Lithium – Wigan CCG leading on this.
- Apomorphine – 1st draft with original authors (SRFT) for updating.
- Modafinil – 1st draft with original authors (SRFT) for updating.
- Riluzole – 1st draft with original authors (SRFT) for updating. K
- Ketamine (palliative care) – 1st draft in development. Need to identify who should give specialist input.

e) Chapter 6

Growth hormone (children) – CMFT preparing a 1st draft.

Growth hormone (adults) – Pennine Acute have reviewed and update existing guideline. This will now be sent out to CCGs/Trusts for comment.

f) Cinacalcet for primary hyperparathyroidism - awaiting GMMMG approval at May meeting.

g) Ibandronate for breast cancer - awaiting GMMMG approval at May meeting

h) Domperidone for paediatric use – CMFT preparing a 1st draft

i) Chapter 1 - Sulfasalazine – not yet started

j) Chapter 8

- Lanreotide – for acromegaly – not yet started.
- Octreotide – for acromegaly – not yet started.

7) 1st Draft SCPs for IPS Discussion

None received this month.

8) Shared Care Protocols for Approval

Denosumab

The group noted that this was the final draft for approval. The group agreed to recommend approval to GMMMG once the following changes had been made:

- Any unused product or waste material should be disposed of in accordance with local requirements – noted not everywhere classes denosumab as cytotoxic/cytostatic waste.
- Specialists should initiate treatment and prescribe first two injections (i.e. first 12 months of treatment).
- Baseline investigations – remove "Monitoring of serum calcium is not required in patients with normal renal function", as serum calcium should be checked prior to each dose of denosumab being administered.
- Ongoing monitoring requirements to be undertaken by GP – remove reference to GPs monitoring patients with creatinine clearance <30ml/min as these patients will be under the care of the specialist for prescribing of denosumab.

ACTION: GM to make changes as above and then send to June 2015 GMMMG for approval.

9) Shared Care Protocols on GMMMG Website to Archive as of May 2015

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

10) Schedule for Review of RAG List and Associated Shared Care Guidelines

The new work plan for the review of the RAG list and associated shared care protocols was circulated for information.

11) Current work plans

The current work plan was circulated for information.

12) Inclusion of Grey/DNP List Drugs on RAG List

At April 2015 IPS meeting it was suggested including drugs on the DNP and Grey Lists on the RAG list for clarity. It was also suggested Grey list drugs may also need a Red/Amber/Green status to define where responsibility for prescribing should lie between primary and secondary care.

A paper was presented to the group for discussion on how this might work in practice.

The group agreed in principle to include DNP/Grey List drugs on the RAG list, and to work with the Formulary Subgroup on this. It was noted that the Formulary Subgroup are currently reviewing the format and content of the DNP/Grey List.

13) Shared Care Protocol Summary – Appendix to SCP Template

An updated template for GMMMG Shared Care Protocols was presented to the group. It now includes a 2 sided A4 summary appendix for prescribers of the SCP. The criteria for shared care and patients excluded from shared care sections have also been move to the start of the document.

It was suggested that in future the full SCP document would be available on the website and that specialists should just forward the Summary Appendix to GPs together with the letter template when requesting GPs to participate in shared care for a particular patient.

The group approved the new template with the summary appendix.

ACTION: GM to send updated SCP template with summary appendix to GMMMG for approval

14) Timings and Dates of Future IPS Meetings

Following discussion the group agreed to remain with the current meeting of time of 1-3pm and to continue to meet on a monthly basis. Workload at each meeting will be kept under regular review and consideration given to alternate monthly meetings at a future date.

15) Supply of Dressings on Discharge from Secondary Care

Item deferred until the June meeting of the IPS.

16) Updates from other groups

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

New Therapies Subgroup

The March meeting of the NTS was cancelled. The NTS is currently preparing recommendations on the following:

- Airsonett device
- Apremilast and Secukinumab for Psoriasis
- Sequential biologics for Psoriasis
- Simbrinza® (brinzolamide/brimonidine) combination eye drops for glaucoma

Formulary Subgroup

Chapter 9 & 13 review now underway. The group is also reviewing an application for Jaydess® (Levonorgestrel intrauterine contraceptive) to be included in the formulary.

GMMMG

The April meeting of GMMMG approved the RAG recommendations following the review of Chapter 6 &11, as well as the recommendations regarding LMWH.

17) AOB

Olanzapine Pamoate Depot Injection

The group discussed the RAG status for Olanzapine Pamoate Depot Injection which is currently listed as AMBER on the RAG list. The group agreed that it should be given a RED RAG status as it required a 3 hour post dose observation period of the patient.

Ondansetron in Paediatrics

A request has been received to review the RAG status of ondansetron in paediatrics. The group agreed that ondansetron use in paediatrics should probably be considered RED as BNFC and SPC only gives information on use for chemo induced N&V and PONV.

There may be some indications where it may be appropriate for GP to be asked to continue prescribing longer term for reasons of practicality and patient convenience but this should be on negotiated on an individual patient basis between the GP and specialist.

Atypical Antipsychotics in Dementia Patients

The group discussed the correspondence received from Dr David Jolley, a consultant psychiatrist working at Willow Wood Hospice in Tameside & Glossop and at Wythenshawe Hospital Memory Service (South Manchester – Manchester Mental Health and Social Care Trust).

The IPS is asked to review its recommendation to change the RAG status of Atypical Antipsychotics in Dementia patients from AMBER to RED made at the January 2015 IPS meeting and subsequently approved by the February 2015 GMMMG meeting.

The group reviewed the relevant sections of the November 2014, December 2014 and January 2015 IPS minutes, and the February 2015 GMMMG minutes detailing how the decision to change the status was taken.

The group also reviewed the comments received from Trusts/CCGs during the original consultation in December 2014.

The group noted that Salford CCG have continued with their existing shared care protocol for atypical antipsychotics, and that Tameside & Glossop CCG are putting in place arrangements

based on the Pennine Care shared care protocol with their GPs around the exceptionality status for the clinic at Willow Wood so that this service can continue as was.

The following key points were raised in the discussions:

- RED status was recommended to ensure these drugs were not started inappropriately in dementia patients without specialist input AND to try & ensure regular review of patients by specialists as recommended by the Prof Banerjee report.
- The group discussed the key recommendations from the Prof Banerjee report (The use of antipsychotic medication for people with dementia: Time for action) in particular the need to reduce levels of antipsychotic prescribing in this patient group, and ensure all prescribing is appropriate.
- Prof Banerjee report showed the number of excess deaths and strokes in resulting from use of antipsychotics in dementia patients. If we apply the figures in Prof Banerjee's report to a population the size of Greater Manchester this would equate to 75 extra deaths and 68 strokes.
- RED status reflects that risperidone is only licensed for 6 weeks treatment. Other antipsychotics are unlicensed, as is longer-term use.
- Mental Health Trusts have capacity issues in managing these patients and associated commissioning issues. These need to be highlighted to commissioners.
- The current shared care protocols from Salford and Pennine Care were discussed and noted that not all CCGs have signed up to these. These are available for CCGs to use to enable local variations in the RED status.
- GPs had concerns that they may not have relevant knowledge and skills to be able to prescribe antipsychotics safely for these patients and accept clinical responsibility.
- Under any shared care there is need to ensure that specialist reviews take place as per NICE CG42 recommendations (e.g. 3 monthly) and GPs have access to support from Specialists. Some felt this was not always the case, and had not been the case when previous AMBER status was in place.
- The previous shared care amber status was in place over the time period that GM became one of the highest prescribers of low dose antipsychotics in dementia patients in the country.
- Concerns that AMBER status may increase the risk of patients not being adequately followed up by specialists, and as a result left on long-term treatment thereby increasing the risk of adverse events e.g. stroke.
- Noted that RED status is causing some difficulties. Not all GPs are flexible to prescribe in exceptional circumstances, but GPs also have the right not accept a patient under a shared care agreement if they feel it is not appropriate or they feel they do not have the clinical competence to do so.
- GPs unlikely to stop these drugs without specialist input, hence risk patients being left on long-term treatment thereby increasing risks.
- Statement needs to be added to introduction stating that RAG list is advisory and where necessary, secondary and primary care prescribers should discuss the appropriate management of individual patients personally. These guidelines are expected to cover the majority of occasions but in exceptional circumstances both parties may agree to work outside of this guidance. In addition where appropriate pathways are in place, some CCGs may have a variation to this list. (*Post-meeting:* This has now been actioned on the GMMMG website).
- Prescribing of antipsychotics in dementia is expected to be short term. In exceptional circumstances, longer term prescribing may be required [which would be outside of the product licence for any drugs which have a marketing authorisation for such use].
- Most GPs would be open to discussion/negotiation with specialist on individual patient basis if the RED status is a barrier to ensuring continuity of supply in specific patients for some reason AND there is not shared care agreement in place within that locality.

After discussion the group felt the RED status for new patients was appropriate but that the wording needed to be updated to reflect the need for GPs to be flexible in exceptional circumstances.

The IPS agreed to further consult with all CCGs/Trusts within GMMMG, and ask them for feedback within their organisation (especially from Old Age Psychiatrists) on the following suggested updated wording to the RAG list (new additional wording in bold below):

Risperidone	4	Atypical antipsychotics (Oral) Use in dementia patients. Local commissioning arrangements may vary and in some localities this remains an amber drug so please check with your CCG. **Prescribing of antipsychotics in dementia is expected to be short term. In *exceptional circumstances*, longer term prescribing may be required [which would be outside of the product licence for any drugs which have a marketing authorisation for such use]. In these situations, there should still be regular review with the aim of reducing or stopping, and the best methods of ensuring continuity of supply should be negotiated between all healthcare professionals involved in that patient's care.**		Red (for new patients only)	CCG

This would still allow for local commissioning arrangements to vary and in some localities for the drugs to remain amber, and reflects the advisory nature of the RAG list and it is hoped that GPs would be flexible to prescribe in exceptional circumstances.

ACTION: GM to update introduction to RAG lists on website to state lists are advisory using wording from IPS Terms of Reference.

GM to draft a response to Dr Jolley for approval by the IPS Chair.

AM to contact Trusts and CCGs with proposed updated RAG status for atypical antipsychotics in dementia for their comments, in particular from old age psychiatrists within their organistation.

Date of Next Meeting: 11th June 2015, 1pm-3pm Room 4100, HMR CCG, Number One Riverside, Smith St. Rochdale OL16 1XU

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