GMMMG Interface Prescribing Subgroup

Minutes

12th March 2015, 1pm-3pm

Croft Shifa Health Centre, HMR CCG
Belfield Road, Rochdale

Present:

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

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

Jason Farrow (JF) Medicines Management Pharmacist, Salford 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

Anna Swift (AS) Medicines Management Pharmacist, Wigan 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

Support:

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

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

In attendance:

Andrew White – Head of Medicines Management, NW CSU
Dr Clare Tower - Clinical Director, SMH (for item 2b)
Dr Louise Byrd - Consultant Obstetrician, SMH (for item 2b)

Apologies received: David OReilly, Lesley Smith, Jeanette Tilstone, and Hong Thoong

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

1) Minutes of the meeting on 12th February 2015.

The minutes were accepted as a true and accurate record.

ACTION: RDTC to publish as final.

2) Matters arising

2a) RAG List Review - Drugs for alcohol dependence (nalmefene, acamprosate and disulfiram)

Correspondence from the Directors of Public Health within Greater Manchester regarding the shared care arrangements and mechanism for prescribing of drugs for alcohol dependence has now been received and was discussed by the group.

At the November & December 2014 meetings of the IPS it the following RAG status for these drugs was proposed:

- Acamprosate & Disulfiram – currently AMBER – suggested not to assign a RAG status but to leave as local decision due to complex commissioning arrangements in this area.
- Naltrexone – currently RED – agreed should change to AMBER. 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.

After further discussion it was agreed that the RAG recommendation of the group should be as follows:

- Acamprosate & Disulfiram – remain AMBER but note that local commissioning arrangements may vary.
- Naltrexone – remain RED – Noted that has higher level of risk and monitoring requirements than acamprosate or disulfiram.
- Nalmefene for alcohol dependence – should be classified as AMBER – this because GP needs to assurance psychosocial support is being provided.

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

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

These were approved by the GMMMG in February 2015 with the exception of the recommendations around LMWH, and the RAG list on the website has now been updated.

The IPS was asked to reconsider its recommendation to GMMMG that prophylactic use of LMWH in pregnancy should be changed from AMBER to RED. The GMMMG was happy with all the other recommendations on RAG status for other indications of LMWH.

The IPS discussed the paper on prophylactic use of LMWH in pregnancy prepared by St Mary's Hospital. The following points were raised in the discussion:

- CMFT used the existing SCP for 88 patients last year.
- Use of LMWH for this indication in some CCGs (e.g. Stockport, Wigan and Salford) has always been RED.
- Under the existing SCP patients are only transferred on a fixed dose for the remainder of the treatment course, are advised to contact secondary care with any queries not the GP, and if no other extra monitoring of their pregnancy/indication for LMWH is required.
- CCGs are concerned about the number of queries they get each week from GPs on use of LMWH in general so want the RAG list to be as clear and simple as possible.
- In their proposed recommendations for LMWH the IPS were trying to make things as clear and simple as possible by having no AMBER category for LMWH.
- These patients attend hospital on two occasions for scans so could they be given a supply of LMWH to last until there next midwife or scan at these visits rather that just 28 days supply.
- GPs expressed concerns about their competence to prescribe LMWH for these patients as they see these patients so infrequently in their practice, and the majority of obstetric care is now provided by secondary care rather GPs.
- The GMMMG RAG list is advisory rather than absolute.

After discussion it was agreed not to change the recommendation to GMMMG that prophylactic use of LMWH in pregnancy be reclassified as RED but that a statement be added saying local commissioning arrangements may vary. This acknowledges that in some CCGs such prescribing may take place under a locally agreed SCP between that particular CCG and CMFT.

The final recommendation on all indications for LMWH to GMMMG will be as follows:

PREVENTION of DVT/PE in MEDICAL & SURGICAL PATIENTS
Prevention of DVT/PE in patients at moderate to high risk.
(Prophylactic dose of LMWH required)

Speciality	Indication	Licensed	Duration	RAG Status	Comments
Oncology	Prophylaxis of VTE in oncology patients on VTE inducing therapy	Dalteparin = N Tinzaparin = N Enoxaparin = N		Red	Commissioning of this service will commence from the 1st April 2015
All Surgical Specialities	Prophylaxis Post-operative use [e.g. hips, knees, general surgical]	Dalteparin = N Tinzaparin = N Enoxaparin = N	Hip = 35 days total Knee = 14 days total Other = as directed by surgeon, up to max of 28 days	Red	
Medicine	Immobile patients or those deemed to be at particularly high risk of DVT at home or in care situation in patients unable to tolerate/take warfarin or NOACs	Dalteparin = Y Tinzaparin = N Enoxaparin = Y	For as long as patient is immobile and/or at higher risk of DVT/PE	Green (following specialist recommendation or advice)	
	For travel prophylaxis in high risk patients (travelling time over 8 hrs) and only as per national recommendations. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2010.08408.x/full	Dalteparin = N Tinzaparin = N Enoxaparin = N		Green (following specialist recommendation or advice)	

PREVENTION of DVT/PE during PREGNANCY and following delivery
Prevention of DVT/PE in pregnant patients at moderate to very high risk.
PLEASE NOTE THE DOSES USED IN PREGNANCY FOR PROPHYLAXIS DIFFER FROM THE USUAL LICENSED DOSES.

MODERATE TO HIGH RISK PATIENTS: NOT ON WARFARIN PRIOR TO PREGNANCY

Speciality	Indication	Licensed	Duration	RAG Status	Comments
Obstetrics / Fertility Clinics	*Use by fertility clinics, and also to prevent miscarriage*	*Dalteparin = N* *Tinzaparin = N* *Enoxaparin = N*		*Red*	
Obstetrics	Prophylaxis of VTE during pregnancy	Dalteparin = N Tinzaparin = N Enoxaparin = N		Red	Local commissioning arrangements may vary and may be amber if local agreement in some CCGs.

Treatment of DVT/PE in all patients
Full anticoagulation of patients with a diagnosis (or working diagnosis) of DVT/PE.
(Treatment dose of LMWH required)

Speciality	Indication	Licensed	Duration	RAG Status	Comments
All Medical & Surgical Specialities	DVT and PE treatment - initial 2 weeks or as per locally agreed pathways	Dalteparin = Y Tinzaparin = Y Enoxaparin = Y	Until warfarin is in range, or scan is negative.	Red	
All Surgical Specialities	Warfarin replacement. Given pre-operatively for up to 5 days up until the day of surgery instead of taking warfarin. Allows INR to fall before operation.	Dalteparin = N Tinzaparin = N Enoxaparin = N	As directed by the surgeon	Red	

All Surgical Specialities	*Given post-operatively in conjunction with warfarin whilst waiting for the INR to come into range.*	*Dalteparin = Y Tinzaparin = Y Enoxaparin = Y*	*Until INR is in range, for a minimum of 6 days treatment.*	*Red*	
Obstetrics	Treatment of DVT/PE in pregnancy. First line treatment of choice.	Dalteparin = N Tinzaparin = N Enoxaparin = N	During pregnancy and for at least 6 weeks post-partum	Red	
Obstetrics	*Patients with mechanical heart valves or those on long term warfarin prior to pregnancy should be discussed by obstetrics/gynaecology consultants with consultant cardiologists/haematologists, ideally before pregnancy.*	Dalteparin = N Tinzaparin = N Enoxaparin = N	*As advised by the specialist. Likely to be throughout pregnancy in place of warfarin.*	*Red*	
Oncology	DVT or PE in oncology patients undergoing cancer therapy or with metastatic disease	Dalteparin = Y Tinzaparin = N Enoxaparin = N	Up to six months treatment	Green (following specialist initiation)	
All Medical & Surgical Specialities	DVT or PE in patient unable to stabilise on warfarin or NOACs, with an allergy or with contra-indication to warfarin and/or NOACs. This includes IVDU patients.	Dalteparin = N Tinzaparin = N Enoxaparin = N	As per intended duration of warfarin treatment. Usually, 3 to 6 months - DVT 6 months - PE OR as stated by initiating consultant	Green (following specialist initiation)	

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

2c) RAG List Recommendations Chapter 4 – now GMMMG approved

These were approved by the GMMMG in February 2015 and the RAG list on the website has now been updated. Following feedback the two AMBER entries for atypical antipyschotics will be combined into one entry to make the list more user friendly.

2d) RAG List Recommendations from January meeting – awaiting GMMMG approval

These are going to March 2015 meeting of GMMMG for final approval.

2e) RAG List Recommendations from February meeting – comments received

These were circulated to Trusts and CCGs for comment.

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

- Testosterone
- Denosumab
- Steroid PF eye drops
- Domperidone
- Apraclonidine eye drops

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			
Domperidone for paediatric use	Amber		Following recent MHRA warnings and new guidance from NICE. CMFT to develop a shared care protocol.
Drugs for alcohol dependence (nalmefene, acamprosate and disulfiram)		✓	Await response to GMMMG letter to public health directors regarding alcohol services.
2) New Requests from New Therapies Subgroup			
None			
RAG List Review – Chapter 6 & 11 (products on formulary currently with no RAG status)			
Denosumab for oncology use	Red		NHS England commissioned and only available via PAS.
Cyproterone acetate for male hypersexuality & prostate cancer	Green (following specialist advice)		
Epotermin alfa (Osigraft®)	Red		Hospital only drug
Disodium pamidronate	Red		
Zoledronic acid	Red		
Teriparatide	Red		Should only be initiated by specialists
Parathyroid hormone	Red		Should only be initiated by specialists
Aflibercept for eye indications	Red		Should only be prescribed and administered by specialists.
Ranibizumab intraviterial injection	Red		Should only be prescribed and administered by specialists.
Pegaptanib sodium	Red		Should only be prescribed and administered by specialists.
Vertoprofin	Red		Should only be prescribed and administered by specialists.
Bevacizumab for eye indications	Red		Unlicensed use
Ocriplasmin intraviterial injection	Red		Should only be prescribed and administered by specialists.
Dexamethasone intraviterial injection	Red		Should only be prescribed and administered by specialists.
Flucinolone acetonide intraviterial implant	Red		Should only be prescribed and administered by specialists.
Apraclonidine eye drops	Red		SPC states for use in perioperative period only.
Ketoralac eye drops	Red		For short-term peri-operative use only.
Sodium chloride 5% eye drops	Red		Unlicensed and for short-term peri-operative use only.
Ofloxacin eye drops	Red		States for Ophthalmic consultants only on formulary.

Cefuroxime eye drops	Red		States for Ophthalmic consultants only on formulary.
Levofloxacin eye drops	Red		States for Ophthalmic consultants only on formulary.
Gentamicin eye drops	Red		States for Ophthalmic consultants only on formulary.
Penicillin eye drops	Red		States for Ophthalmic consultants only on formulary.
Amikacin eye drops	Red		States for Ophthalmic consultants only on formulary.
Propamidine eye drops	Green		Available as Golden eye OTC
Dibrompropamide eye ointment	Red		States for Ophthalmic consultants only on formulary.
PHMB eye drops	Red		States for Ophthalmic consultants only on formulary.
Chlorhexidine eye drops	Red		States for Ophthalmic consultants only on formulary.
Ganciclovir eye drops	Red		States for Ophthalmic consultants only on formulary.
Aciclovir eye ointment	Green		
Trifluorothymidine eye drops	Red		States for Ophthalmic consultants only on formulary.
Fluorometholone eye drops	Red		States for Ophthalmic consultants only on formulary.
Acetazolomide tablets for opthalamic indications	Green (following specialist initiation)		States for Ophthalmic consultants initiation only on formulary.
Steroid preservative free eye drops (N.B. not Minims)	Green (following specialist initiation)		Unlicensed
4) Changes to current RAG status – Chapter 6 & 11			
Pegvisomat	Red		Change from Amber. NHSE commissioned.
Testosterone products	Green (following specialist advice)		Change from Green
5) No changes to current RAG status – Chapter 6 & 11			
Infertility drugs	Red		No change
Denosumab for osteoporosis	Amber		No change
GLP-1 agonists	Green		No change
Growth hormone (children)	Amber		No change
Growth hormone (adults)	Amber		No change
Ibandronic acid (breast cancer)	Amber		No change
Insulin + GLP-1	Green (following specialist initiation)		No change
LHRH analogues	Amber for licensed indications		No change

Metformin for PCOS	Green		No change
Pegvisomat	Amber		No change
Propylthiouracil	Green (following specialist initiation)		No change
Glitpins	Green		No change
Stanozolol	Red		No change
Tolvaptan	Red		No change
6) Miscellaneous Decisions			
Sodium valproate in epilepsy	Green (following specialist advice)		No change but need to highlight recent MHRA drug safety update re use in women of child bearing potential.

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

2f) Antidementia drugs leaflets – awaiting GMMMG approval

These are going to March 2015 meeting of GMMMG for final approval following consultation with all the local Mental Health Trusts.

2g) Chapter 10 SCP Review

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

2h) Chapter 9 SCP Review – hydroxycarbamide

Following discussion at January 2015 IPS meeting the proposed draft SCP is currently being updated with input from the haematologists at CMFT. A draft should be ready for discussion at the April meeting of the IPS.

2i) Chapter 5 SCP Review – 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 by the 1st draft is ready for external comment.

2j) Chapter 4 SCP Review

Work has begun on producing GMMMG versions of the agreed list of SCPs for chapter 4 from the January 2015 IPS meeting. For information:

ADHD drugs – 2nd draft has been sent to Pennine Care and CMFT (the original authors) for comment. Aim is to send to other CCGs/Trusts for comment in March and to approve final draft at April/May meeting of IPS.

Melatonin – was approved at February 2015 meeting of GMMMG.

2k) Chapter 6 SCP Review - Denosumab

Denosumab - A first draft of this SCP has been prepared and sent to the original author at UHSM and IPS members for comment by the end of March 2015. A final draft will ready for external comment for April 2015 IPS meeting.

Ibandronate for breast cancer – the draft was presented to the IPS for discussion. It was suggested to add information about atypical fractures and reduced dose in renal failure. The group agreed that

once these changes have been made that it could now be sent out to CCGs and Trusts for further comments.

ACTION: GM/AM to send Ibandronate SCP to CCGs and Trusts for further feedback.

2l) Transgender use of hormonal therapy

Following discussion at the February meeting of the IPS it has been confirmed that use of hormone therapy by Gender Identity Services is classed as AMBER by NHS England and there is a national shared care protocol template available to support this.

As such the IPS agreed to add these drugs to the GMMMG RAG list as AMBER drugs for this indication.

ACTION: GM to send final recommendation on RAG status of these drugs to the April meeting of GMMMG for approval.

GM to update RAG list and publish on website once approval received from GMMMG

3) Chapter 3 RAG list review – drugs for review

- **a)** Dornase alfa – currently Amber – recommended be classified as RED as now NHS England Commissioned and as such has been repatriated to secondary care.
- **b)** Omalizumab – currently Red – no changed recommended.
- **c)** Bee & wasp allergen (Pharmalgen®) – no status - recommended be classified as RED.
- **d)** Pirfenidone – no status (currently Red on the formulary) - recommended be classified as RED.
- **e)** C1-esterase inhibitor – no status - recommended be classified as RED.
- **f)** Conestat alfa – no status - recommended be classified as RED.
- **g)** Icatibant – no status - recommended be classified as RED.
- **h)** Ivacaftor – no status - recommended be classified as RED.
- **i)** Grass Pollen Extract – no status – recommended no status required as on DNP list.
- **j)** Poractant alfa (Curosurf®) – no status - recommended be classified as RED.
- **k)** Mannitol inhaler – no status - recommended be classified as RED as NHSE commissioned.
- **l)** Salbutamol injection – no status (currently Red on the formulary) - recommended be classified as RED.
- **m)** Aminophylline injection – no status - recommended be classified as RED.
- **n)** Azathioprine for interstitial lung disease – no status - recommended be classified as RED as unlicensed and not recommended by NICE. Formulary subgroup to consider adding to DNP list.

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

Formulary subgroup to review NICE Do Not Do List and compare with GMMMG DNP list

4) Chapter 3 Shared Care Protocol review – existing guidelines

The existing Share Care Protocols for drugs within Chapter 3 were reviewed:

- Pulmozyme nebuliser solution in CF patients – from UHSM

It was agreed that this SCP was no longer required due to change in RAG status from AMBER to RED.

ACTION: GM to archive SCP for pulmozyme on GMMMG website.

5) Chapter 3 Shared Care Protocol review – drugs without an SCP

None were identified as requiring a shared care protocol.

6) Chapter 12 RAG list review and Shared Care Protocol review
There are currently no drugs classified as Red or Amber, and no SCPs in Chapter 12, and no drugs were identified as requiring a Red or Amber status.

7) Chapter 13 RAG list review – drugs for review

- **a)** Acitretin – currently Red – no change recommended.
- **b)** Alitretinoin – currently Red – no change recommended.
- **c)** Botulinum toxin – currently Red – no change recommended.
- **d)** Isotretinoin (oral) – currently Red – no change recommended.
- **e)** Tacrolimus ointment – no status (For initiation by specialist only on formulary) – recommended be classified as Green (following specialist advice).
- **f)** Pimecrolimus – no status (For initiation by specialist only on formulary) - recommended be classified as Green (following specialist advice).
- **g)** Dithranol (licensed preps) – no status - recommended be classified as Green (following specialist advice) and formulary subgroup to review inclusion in formulary as it is largely the unlicensed preparations that are currently used.
- **h)** Dithranol (unlicensed preps) – no status - recommended be classified as Red as unlicensed.
- **i)** Ustekinumab – no status - recommended be classified as RED as it is a monoclonal antibody.
- **j)** Dapsone – no status - recommended be classified as Green (following specialist advice) as no special monitoring requirements
- **k)** DMARDs when used in dermatology (Ciclosporin, Oral Methotrexate, Azathioprine, Mycophenolate) – no status - recommended be classified as AMBER as per all the other DMARD indications.

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

8) Chapter 13 Shared Care Protocol review – existing guidelines
There are currently no existing shared care protocols in Chapter 13 of the RAG list and following the RAG list review it was identified that the following SCPs were required:

- DMARDs when used in dermatology

ACTION: GM to include dermatology indications for DMARDs when DMARD SCPs for rheumatology are finalised in summer of 2015.

9) Strontium – review of RAG status
Item deferred until the next meeting of the IPS.

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

- **a)** DuoResp® (Budesonide/formoterol) inhaler – Item deferred until the next meeting of the IPS.
- **b)** Tapentadol – not for routine prescribing – Item deferred until the next meeting of the IPS.
- **c)** Relvar® inhaler – Item deferred until the next meeting of the IPS.
- **d)** Nabilone for the treatment of chronic non cancer pain (unlicensed indication) – Item deferred until the next meeting of the IPS.

11) Shared Care Protocols for Approval
Cinacalcet for primary hyperparathyroidism - Item deferred until the next meeting of the IPS.

12) Current work plans
The current work plan was circulated for information.

13) Updates from other groups.
Not discussed this month but summary provided below for information.

New Therapies Subgroup

Feb meeting looked at Tiotropium for asthma, Safinamide (Xadago®) for Parkinson's disease and Naltrexone/bupropion (Mysimba®) for obesity.

Formulary Subgroup

Chapter 7 & 10 reviews completed.

Chapter 9 & 13 review now underway.

GMMMG

The February meeting of GMMMG approved the LHRH in prostate cancer SCP.

14) AOB

Denosumab – oncology indications

The IPS confirmed should be classified as RED on the RAG list and this will be communicated to The Christie. This is because it is only available via a Patient Access Scheme.

Date of Next Meeting: 9th April 2015, 1pm-3pm Room 4100, HMR CCG, Number One Riverside, Smith St. Rochdale OL16 1XU

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