

Minutes of the Lancashire Medicines Management Group Meeting Held on Thursday 10th March 2016 at Preston Business Centre

PRESENT:

Dr Tony Naughton (TN) Chair of LMMG Lancashire CCG Network Christine Woffindin (CW) Medicines Information Manager East Lancashire Hospitals NHS Trust Dr Catherine Fewster (CF) Lancashire Care NHS Foundation Trust Chief Pharmacist Senior Operating Officer Primary Care, NHS Blackburn with Darwen CCG Julie Kenyon (JK) Community & Medicines Assistant Director - Medicines Melanie Preston (MP) NHS Blackpool CCG Optimisation Dr Lisa Rogan (LR) Head of Medicines Commissioning NHS East Lancashire CCG NHS Greater Preston CCG, NHS Chorley Head of Medicines Optimisation Clare Moss (CM) and South Ribble CCG Senior Manager - Medicines NHS Lancashire North CCG Graham Atkinson (GA) Optimisation NHS Lancashire North CCG Dr Kamlesh Sidhu (KS) **GP Prescribing Lead** Nicola Baxter (NB) Head of Medicines Optimisation NHS West Lancashire CCG Pauline Bourne (PB) Senior Pharmacist, Medicines University Hospitals of Morecambe Bay Management, Deputy Chief **NHS Foundation Trust Pharmacist** Head of Medicines Optimisation NHS Fylde and Wyre CCG Julie Lonsdale (JL) Lancashire Teaching Hospitals NHS David Jones (DJ) Assistant Chief Pharmacist Foundation Trust IN ATTENDANCE: Brent Horrell (BH) Head of Medicines Commissioning NHS Midlands and Lancashire CSU Susan McKernan (SM) Senior Medicines Performance NHS Midlands and Lancashire CSU **Pharmacist** NHS Midlands and Lancashire CSU Sarah Newsome (SN) Medicines Commissioning Technician Jane Johnstone (Minutes) Medicines Management Administrator NHS Midlands and Lancashire CSU

ITEM	SUMMARY OF DISCUSSION	ACTION
2016/042	Welcome & apologies for absence	
	The chair welcomed everyone to the meeting. It was noted that Sarah Newsome, Medicines Commissioning Technician M&LCSU was in attendance to observe the meeting.	
	Apologies for absence were received on behalf of Alastair Gibson and Dr John Randall and David Prayle.	
2016/043	Declaration of any other urgent business	
	None.	
2016/044	Declarations of interest pertinent to agenda	
	None.	

ITEM	SUMMARY OF DISCUSSION	ACTION
2016/045	Minutes of the last meeting (11 th February 2016) The minutes of the meeting dated 11 th February 2016 were agreed as a true and accurate record subject to the following amendments:	
	Agenda item 2016/031 Draft Colour classification review list Oncology Prophylaxis of VTE in oncology patients on VTE inducing therapy – Amber 1 colour classification – this will be brought back to LMMG for further discussion due to this being red colour classification in some CCGs.	
	Surgical Page 8, the text will be amended to read: All Surgical Specialities: Post-operative use in conjunction with warfarin whilst waiting for the INR to come into range. (If LMWH is indicated at discharge it is expected that secondary care will provide the initial supply and arrange for the patient to been seen through their normal place of care, from which further supplies will be provided if indicated) – Red colour classification.	Both actions SM
2016/046	Matters arising (not on the agenda)	
	None.	
NEW MEDIC	CINES REVIEWS	
2016/047	Insulin glargine 300 units/mL in Type 1 and Type 2 Diabetes Mellitus	
	This paper was brought for further discussion as a recommendation was not made at the January and February LMMG for Insulin glargine 300 units/mL in Type 1 and Type 2 Diabetes.	
	The committee considered the evidence reviews, consultation responses, MHRA Drug Safety update and the UKMI risk assessment. Following discussion, it was agreed that there were inherent risks with all RAG recommendations, that the risks could be managed and should not define the RAG recommendation of the LMMG.	
	Decision The committee agreed on an Amber0 colour classification for Insulin glargine 300 units/mL in Type 1 and Type Diabetes Mellitus. This will be put onto the website together with the MHRA Drug Safety update.	

ITEM	SUMMARY OF DISCUSSION	ACTION
	It was also agreed that the CSU will draft a supporting document for use by member organisations to support education of prescribers.	
	Action DJ will forward a safety procedure for high strength insulin glargine to support the development of a supporting document.	DJ
	Insulin glargine 300 units/mL in Type 1 and Type 2 Diabetes Mellitus will be put on the LMMG website as Amber0 colour classification together with the MHRA drug safety information.	вн
2016/048	Tadalafil daily	
	BH presented the paper; summarising the evidence and the draft recommendation which had been consulted on, as follows:	
	Recommendation	
	Prescribing within specialist Sexual Health service - Red	
	Tadalafil 2.5 mg and 5 mg once daily tablets are recommended for prescribing in Lancashire only when provided by a specialist Sexual Health service as treatment for erectile dysfunction in the following circumstances:	
	 where performance anxiety is significant and/or to support masturbatory/behavioural programs, whereby the erection would require additional support to enable the program to be successful. 	
	Prescribing within Primary Care - Black	
	Outside of the group of patients and circumstances defined by the LMMG where treatment is provided by a specialist Sexual Health service, tadalafil 2.5 mg and 5 mg once daily tablets are not recommended for prescribing in Lancashire for the treatment of erectile dysfunction:	
	 where up to and including twice weekly dosing of on demand tadalafil is required or 	
	 where more than twice weekly dosing of on demand tadalafil is required 	
	6 of 8 CCGs, 2 of 4 acute trusts and Lancashire Care Trust responded by the closing date. All six CCGs who responded agreed with the recommendation. One Acute Trust agreed with the assessment, East Lancashire Hospitals NHS Trust disagreed. LCFT agreed with the assessment.	
	The committee discussed the following consultation comments:	

ITEM	SUMMARY OF DISCUSSION	ACTION
	Blackpool CCG suggested that prescribing should not be initiated outside of the specialist Sexual Health Service; the committee agreed that this will be highlighted in the recommendation.	
	ELHT suggested widening the patients eligible for treatment under Amber traffic light status as follows: Post radical prostatectomy (prostate cancer) patients as part of penile rehabilitation - it was noted that, previous work by LMMG on erectile dysfunction had concluded that the evidence base for use in this patient cohort was weak and that expected patient numbers were small. The specialists had not requested that this group of patients was considered within the evidence review.	
	The decision regarding use of tadalafil in post radical prostatectomy will be deferred pending further discussion at the April LMMG as this patient cohort was not specifically considered in the evidence review discussed at LMMG.	
	Young patients with ED who have a sexual frequency of more than 2 per week and who demand more spontaneity - BH highlighted that this falls under the DOH general advice for prescribing of PDE5i and was therefore already covered in the Black traffic light recommendation.	
	Comments were received from the Psychosexual Service which highlighted supply and transfer issues in the service. The comments were noted and it was felt these did not contribute to the recommendation of the LMMG colour classification but should be highlighted to the Commissioner of the service.	
	In the Details of Review table, a footnote will be added to clarify that this wording relates to the requested place in therapy, and that the LMMG recommendation is for patients to remain in the specialist service until they no longer require treatment.	
	Decision The committee agreed with the recommendation of a Red colour classification for prescribing within specialist sexual health services and a Black colour classification for all other prescribing within primary care including post radical prostatectomy.	All actions BH
	Actions Include in the recommendation prescribing should not be initiated outside of the Specialist sexual Health Service.	
	A sentence will be added to the Details of Review table to clarify that this relates to the requested place in therapy not the LMMG recommendation.	
	Tadalafil daily will be put on the website as Red colour	

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	classification Prescribing within specialist Sexual Health service.	
	Post radical prostatectomy will not be added to the LMMG website until further discussions take place at the April LMMG.	
2016/049	Etanercept biosimilar position statement	
	BH presented this paper which was drafted following the launch of a biosimilar of etanercept and approval of the Insulin Glargine biosimilar and Infliximab biosimilar position statements.	
	The draft recommendation was:	
	Red Biosimilars of etanercept (Enbrel®) are recommended within their licensed indications. The prescribing of biosimilar preparations should be by brand name, followed by the concentration and recommended daily dose in units and a statement of the formulation. The preparation with the lowest acquisition cost (taking into account administration costs, dosage and price per dose) should normally be used.	
	There was a discussion about the potential for biosimilar contract prices to change over time and about the differences in stability between biosimilar products. It was agreed that it may not always be appropriate to switch patients stabilised on treatment, or to change formulary choice based on minor price variations. It was therefore agreed that the following sentence will be reworded to acknowledge these complexities: "The preparation with the lowest acquisition cost (taking into account administration costs, dosage and price per dose) should normally be used."	
	It was noted that this discussion was also relevant to the infliximab biosimilar position statement and it was agreed that this would also be updated to reflect the same.	
	Decision The committee approved the position statement for biosimilars of etanercept (Enbrel®) subject to the amendment of the sentence regarding use of the biosimilar with the lowest acquisition cost, to reflect the complexities of product selection.	
	Action BH will reword the sentence in line with the discussion above.	All actions BH
	The position statement will be uploaded to the LMMG website as a red colour classification.	

ITEM	SUMMARY OF DISCUSSION	ACTION
2016/050	LMMG – New Medicine Reviews Work Plan update	
	BH discussed the paper; updating the committee on the current status of the work plan as follows:	
	Medications for recommendation for April LMMG Second line use of biologics – Crohn's – Local gastroenterologists have been asked to feedback on this work and to input into the development of a biologics pathway for Crohn's. No feedback has been received at this stage. It was agreed that in the absence of responses this will be sent out to consultation.	
	Second line use of biologics – Ulcerative Colitis – Local gastroenterologists have been asked to feedback on this work and to input into the development of a biologics pathway for ulcerative colitis. No feedback has been received at this stage. It was agreed that in the absence of responses this will be sent out to consultation.	
	Sodium Oxybate – Narcolepsy with cataplexy - this is currently out to consultation.	
	Peristeen/Qufora – Transanal Irrigation/Rectal Irrigations Systems – this will be brought to the April meeting for consideration.	
	<u>Medications for recommendation for May LMMG</u> Ullipristal (Esmya) – Uterine Fibroids – SMC has published their guidance, a summary will be sent out imminently.	
	Liothyronine – Persisting Lethargy despite levothyroxine replacement/Thyroid cancer awaiting ablative treatment - this is currently in the process of being drafted.	All actions BH
	Medications for discussion Melatonin – Treatment of insomnia in older adults with REM Sleep Behaviour Disorder (RBD) – this was discussed following a request received on the 1 st March 2016. The committee agreed that consistency across Lancashire is required and therefore a working group will be established to discuss the issues further, volunteers to be part of the working group were CF, (CF also suggested representation from CAMHS), NB, LR and GA.	
	New Medicines Reviews – for future review Biologics Pathway – Psoriasis – biologics pathway has previously been developed in GMMMG Tapentadol prolonged release – Severe chronic pain Lurasidone – Schizophrenia Infliximab – Pyoderma Gangrenosum – a small number of requests have been received and considered via IFR, to develop commissioning position following clarification of place in therapy	

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	with dermatologists. Guanfacine – ADHD – agreed for addition to the work plan at the February 2016 LMMG. Eluxadoline – Irritable bowel syndrome – diarrhoea predominant – agreed for addition to the work plan at the February 2016 LMMG. Colesevelam – Familial hypercholesterolemia – agreed for addition to the work plan at the February 2016 LMMG. However, highlighted as not as high a priority as a number of the other requests.	
	Medications currently on hold – Awaiting Licensing and Launch Albiglutide/Dulaglutide – Diabetes Naltrexone/bupropion – Obesity Bazedoxifen/conjugated oestrogen – post menopausal osteoporosis + menopausal symptoms Safinamide – Mild-late stage Parkinson's disease Liraglutide – Obesity Insulin degludec & insulin aspartate (Ryzodeg®) – Type II Diabetes – there are no plans for the launch of this product and therefore this will be removed from the work plan.	
	therefore this will be removed from the work plan.	

GUIDELINES and INFORMATION LEAFLETS

2016/051 Mycophenolate shared care

SM presented this paper which was developed to support the offlicense use of Mycophenolate Mofetil for a range of indications.

Responses were received from 4 CCGs and 4 provider Trusts. Of those organisations which replied, 5 supported the guidance, 2 organisations did not specify and 1 organisation did not support the shared care guidance because they considered that the mycophenolate should be classed as Red for these indications.

MP highlighted that the colour classification of mycophenolate for these indications will be discussed further within the CCG and therefore asked for their initial comments to be disregarded.

The committee discussed and decided the following:

Further clarity was needed regarding the mechanism of sharing test results because it was unclear if the 'copy to' function on pathology forms could be accessed by all organisations. It was suggested that this should be aligned with the process outlined in the Rheumatology Shared Care guidance.

"Monitoring required in Primary Care" - for clarity, the monitoring

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	will be updated to confirm that for the first 3 months the monitoring will be undertaken in secondary care, then monthly in primary care.	
	LR asked that Interstitial Lung Disease was included within the shared care guidance.	
	It was agreed that further information was required in order to allow LMMG members make a decision around the appropriateness of each indication, for shared care.	
	Decision The committee agreed further clarity was required around the appropriateness of each indication for shared care, before the document could be approved.	All actions SM
	Action SM to collate the necessary information for consideration at a future LMMG.	
2016/052	NOAC prescribing guide	
	SM presented this paper which has been updated following the publication of NICE TA355.	
	Under 4.5 NOAC Monitoring Requirements SM will amend the sentence beginning: "However, patients at high risk of bleeding should be monitored for signs and symptoms of bleeding complications and anaemia after initiation of anticoagulation."	
	to the following: "For all NOACs, patients at high risk of bleeding should be monitored for signs and symptoms of bleeding complications and anaemia after initiation of anticoagulation."	
	The committee discussed and decided that the NOAC Prescribing Guide will be merged with the anticoagulant consensus statement and the oral anticoagulant decision aid, to make oral anticoagulants in AF prescribing guide, this will require information on the use of warfarin to be incorporated. It was agreed that further input from local experts and consideration of the wider range of NOAC prescribing resources would also be useful. Decision	
	The amendments made following consultation responses were discussed and approved.	
	Action	

ITEM	SUMMARY OF DISCUSSION	ACTION
	SM will amend the paragraph to include "For all NOACs" as highlighted above.	
	The NOAC prescribing guide will be uploaded to the LMMG website.	
	The Oral anticoagulants in AF prescribing guide will be added to the work plan	
2016/053	Oral anticoagulant decision aid and patient counselling checklist	
	SM presented this paper which has been updated following the publication of NICE TA355, with information on edoxaban.	
	Responses were received from 5 CCGs and 3 provider Trusts; 6 supported the guidance, 2 organisations did not specify either way.	
	SM said that she would investigate making the oral anticoagulant decision support tool available as a template via EMIS web.	
	Decision The committee discussed and approved the amendments made following consultation responses.	
	Action The Oral anticoagulant decision aid and patient counselling checklist will be uploaded to the LMMG website.	SM
2016/054	Neuropathic pain guidance – update	
	SM discussed this paper which had been updated in light of the recommendation at the February LMMG for the use of Lidocaine Patches for the treatment of localised neuropathic pain with predominance of allodynia and/or hyperalgesia and dysesthesias unresponsive to other neuropathic agents within specialist services only.	
	Decision The committee approved the amendments made.	
	Action The neuropathic pain guidance document will be uploaded to the LMMG website.	SM
2016/055	Riluzole Shared Care Guidance – update	
	SM discussed the amendments made to the Riluzole shared care guidance following the availability of the newly licensed liquid	

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	preparation of Riluzole.	
	Decision The committee approved the Riluzole shared care guidance.	
	Action The contact details and the patient ID Label boxes at the top of the guidance will be removed.	Both actions SM
	The Riluzole shared care guidance will be uploaded to the LMMG website.	Both actions SM
2016/056	LMMG – Guidelines Work Plan update	
	SM discussed this paper; updating LMMG on the current status of the work plan, as follows:	
	Due for discussion /approval at the April meeting Biologics in RA Pathway-update.	
	In development Constipation guideline – scoping document, currently out to consultation.	
	Best practice guideline for ordering and supply of continence and stoma products – identified from Transanal Irrigation work.	
	Neuropathic Pain Patient Information Leaflet – a request has been received to incorporate a patient information leaflet on neuropathic pain into the guidance document. The committee agreed that this will be added to the work plan.	SM
	Decision Aid for Antivirals During Flu outbreaks – in response to a recent increase in circulating influenza virus a request has been received for up to date guidance on the diagnosis and appropriate management of flu and suspected flu, including an antiviral decision aid. It was noted that PHE leads on this work stream and that existing information provided from them is now dated. SM will raise concerns with PH and feedback to the Committee.	SM
	Other LMMG Work Co-Trimoxaxole Shared Care Guideline – on hold, awaiting feedback from secondary care regarding management of abnormal blood results.	
	Apomorphine Shared Care Guidelines – LMMG comments have been feedback to LTHTR. Awaiting confirmation of lead for this work in order to progress further.	

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	Palliative Care Prescribing Guidelines - awaiting further feedback from the SCN regarding the format of the guidelines and the geographical area that they will cover.	
NATIONAL	DECISIONS FOR IMPLEMENTATION	
2016/057	New NICE Technology Appraisal Guidance for Medicines (February)	
	SM presented this paper, the following actions were agreed:-	
	TA385 Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolemia - this is a CCG commissioning responsibility. The committee agreed a Green colour classification. This will be added to the LMMG website.	
	TA383 TNF – alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis – this is a CCG commissioning responsibility. The committee agreed a Red colour classification. This will be added to the LMMG website. A blueteq form will be created.	All actions SM
	TA384 Nivolumab for treating advanced (unresectable or metastatic) melanoma – this is an NHS England commissioning responsibility and was brought for information. This will be added to the LMMG website.	
2016/058	New NHS England medicines commissioning policies (January and February 2016)	
	This item is deferred to the April LMMG.	
2016/059	Evidence reviews published by SMC or AWMSG (December 2015, January 2016)	
	BH discussed the SMC and AWMSG recommendations published during December 2015 and January 2016 meeting LMMG criteria, which were:	
	December 2015 and January 2016 1104/15 Ivermectin (Soolantra®) SMC accepted Ivermectin (Soolantra®) for the treatment of inflammatory lesions of rosacea (papulopustular) in adult patients. The committee decided that a summary of the SMC evidence review will be undertaken and sent out to consultation. This will be added to the work plan. 1024/15 Albiglutide (Eperzan®) SMC accepted Albiglutide (Eperzan®) for the treatment of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose-lowering medicinal products	All actions BH

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	including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. The committee decided than an evidence review of the GLP-1s will be carried out. This will be added to the work plan.	
	1110/15 Dulaglutide (Trulicity®) SMC accepted Dulaglutide (Trulicity®) for the treatment of type 2 diabetes mellitus in adults to improve glycaemic control as add-on therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. The committee decided that an evidence review of the GLP-1s will be carried out. This will be added to the work plan.	
	It was noted that there were no AWMSG evidence reviews published in December 2015 and January 2016 which met the LMMG criteria.	
	It was discussed that the remaining SMC and AWMSG recommendations for December 2015 January 2016 did not meet LMMG criteria; therefore the committee agreed that no further action would be taken with regard to them.	
	The February 2016 evidence reviews published by SMC or AWMSG are deferred and will be brought to the April LMMG.	
PROCESS P	ROPOSALS	
2016/060	Process for Annual Declarations of Interest	
	BH discussed the proposed process for the provision of annual declarations for LMMG members.	
	For clarification it was highlighted that declarations of interest should be pertinent to the committee members' current role unless there is some other significant interest which would have a bearing on any work related to their current role.	
	A question was raised regarding the dissemination of consultations to wider organisations and how those potential declarations of interest could be captured. It was decided that a sentence will be added to the consultation email which requests declarations of interest from any individual who provides comments on the consultation. These will then be recorded.	
	Decision A sentence will be added to the consultation email regarding declarations of interests when the consultation is disseminated for wider comment.	вн

ITEM	SUMMARY OF DISCUSSION	ACTION		
	The committee members decided that the process for annual declarations will be adopted.			
ITEMS FOR INFORMATION				
2016/061	Minutes of the Lancashire Care FT Drug and Therapeutic Committee (January 2016)			
	The committee noted these minutes.			
2016/062	Minutes of the Lancashire CCG Network (January 2016)			
	The committee noted these minutes.			

Date and time of the next meeting 14th April 2016, 9.30 am to 11.30 am, Meeting Room 253, Preston Business Centre

ACTION SHEET FROM THE LANCASHIRE MEDICINES MANAGEMENT GROUP 10th March 2016

MINUTE NUMBER	DESCRIPTION	ACTION	DATE	STATUS AT 10.03.2016	
ACTION SHEET FROM THE 14 JANUARY 2016 MEETING					
2016/008 and 009	Insulin glargine 300 units/mL in Type 1 and Type 2 Diabetes Mellitus LMMG members will take this to their local Medicines Groups to consider the risks and benefits of Insulin Glargine 300 units/mL (Toujeo®) in Type 1 Diabetes alongside the evidence in Type 2 Diabetes. Update: discussed under an agenda item.	LMMG Members	04.02.2016	Closed	
	ACTION SHEET FROM THE 11 th FEBRUARY 2016 MEETING				
2016/028	Horizon Scanning 2016/17 Financial Year Evolocumab for treating primary hypercholesterolemia and mixed dyslipidaemia - NICE guidance is due in April 2016; BH suggested that this potential significant cost pressure should be highlighted to commissioners. Update: BH asked the MM Leads to highlight this information to commissioners.	MM Leads	03.03.2016	Closed	
	Licensed version of e-cigarettes - JK will forward the letter from BwD Council to MLCSU for circulation and MLCSU will engage with Public Health with a view to publishing a joint statement. Update: JK will forward this.	JK BH	07.04.2016	Open	
	Secondary Care MM Leads will circulate the Horizon scanning document to specialists to seek their preferences for prioritising products which are due to be licensed. Update: no feedback has been received; this will be brought to the April LMMG.	Secondary Care MM Leads	07.04.2016	Open	
ACTION SHEET	FROM THE 10 th MARCH 2016 MEETING				
2016/047	Insulin glargine 300 units/mL in Type 1 and Type 2 Diabetes Mellitus				
	Action: DJ will forward a safety procedure leaflet for high strength insulin glargine.	DJ	07.04.2016	Open	

2016/056	LMMG – Guidelines Work Plan update			
	Decision Aid for Antivirals During Flu outbreaks	SM	07.04.2016	Open
	Action: SM will contact PH to raise concerns around a lack of up to date prescribing information.			