Minutes of the Lancashire Medicines Management Group Meeting
Held on Thursday 14th April 2016 at Preston Business Centre

PRESENT:

Dr Tony Naughton (TN)	Chair of LMMG	Lancashire CCG Network
Alastair Gibson (AG)	Director of Pharmacy	Blackpool Teaching Hospitals NHS Foundation Trust
Christine Woffindin (CW)	Medicines Information Manager	East Lancashire Hospitals NHS Trust
Dr Catherine Fewster (CF)	Chief Pharmacist	Lancashire Care NHS Foundation Trust
Melanie Preston (MP)	Assistant Director - Medicines Optimisation	NHS Blackpool CCG
Nicola Schaffel (NS)	Lead Medicines Optimisation Pharmacist	NHS Greater Preston CCG, NHS Chorley and South Ribble CCG
Graham Atkinson (GA)	Senior Manager – Medicines Optimisation	NHS Lancashire North CCG
Dr Kamlesh Sidhu (KS)	GP Prescribing Lead	NHS Lancashire North CCG
Judith Argall (JG)	Drug and Therapeutics Pharmacist	Lancashire Teaching Hospitals NHS Foundation Trust
Pauline Bourne (PB)	Senior Pharmacist, Medicines Management, Deputy Chief Pharmacist	University Hospitals of Morecambe Bay NHS Foundation Trust
Julie Lonsdale (JL)	Head of Medicines Optimisation	NHS Fylde and Wyre CCG

IN ATTENDANCE:

Brent Horrell (BH)	Head of Medicines Commissioning	NHS Midlands and Lancashire CSU
Susan McKernan (SM)	Senior Medicines Performance Pharmacist	NHS Midlands and Lancashire CSU
David Prayle (DP)	Senior Medicines Commissioning Pharmacist	NHS Midlands and Lancashire CSU
Jane Johnstone (Minutes)	Medicines Management Administrator	NHS Midlands and Lancashire CSU

ITEM	SUMMARY OF DISCUSSION	ACTION
2016/063	**Welcome & apologies for absence** The Chair welcomed everyone to the meeting. Apologies for absence were received on behalf of Clare Moss, Nicola Baxter, Julie Kenyon, Lisa Rogan and David Jones It was noted that Judith Argall was attending on behalf of David Jones and Nicola Schaffel on behalf of Clare Moss.	
2016/064	**Declaration of any other urgent business** None.	
2016/065	**Declarations of interest pertinent to agenda** None.	

2016/066	**Minutes of the last meeting (10th March 2016)** The minutes of the meeting dated 10th March 2016 were agreed as a true and accurate record subject to the following amendments: **2016/048 Tadalafil daily** The following sentences highlighted in bold will be removed from the minutes pending further discussions of the ED Guideline at the April LMMG. Page 4 remove the sentence **"It was therefore felt that this would fall under the black colour classification**" - (for Post radical prostatectomy (prostate cancer) patients as part of penile rehabilitation) Page 4 remove the words **"Post meeting amendment."** <u>The minute on page 4 will now read as follows:</u> 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. Page 5 remove the sentence **"Tadalafil daily will be put on the website as Black colour classification prescribing within Primary Care including post radical prostatectomy."** Page 5 remove the words **"Post meeting amendment."** <u>The minute on page 5 will now read as follows:</u> Post radical prostatectomy will not be added to the LMMG website until further discussions take place at the April LMMG.	
2016/067	**Matters arising (not on the agenda)** There were no matters arising.	
NEW MEDICINES REVIEWS		
2016/068	**Sodium Oxybate – Narcolepsy with Cataplexy** DP presented the paper, summarising the evidence and the draft recommendation which had been consulted on, as follows: **Recommendation: Black** Sodium oxybate is not recommended for use as a treatment of narcolepsy with cataplexy. The evidence demonstrates sodium oxybate's efficacy when used for the treatment of narcolepsy with cataplexy. There are however significant concerns, as follows: • The only UK based cost effectiveness estimate, which was	

	provided by the SMC, estimated sodium oxybate's cost per QALY to be between £49,590 and £65,980. The SMC review also raised concerns that the potential costs of adverse events had not been included in the costing model and that the clinical resource savings may not be realised. This led the SMC to conclude that the drug was not cost effective. • Safety issues and side effects, particularly respiratory depression are significant Sodium oxybate is a schedule 2 Controlled Drug with an abuse potential. 4 of 8 CCGs, all 4 acute trusts and Lancashire Care Trust responded by the closing date. All four CCGs who responded agreed with the recommendation. Three Acute Trusts agreed with the assessment. One Acute Trust and Lancashire Care (Mental Health Trust) did not feel able to comment as sleep services are outside the scope of Trusts' services. A comment by a Clinical Director of Neurology at LTHTH was received after the circulation of the agenda papers and discussed at the meeting. This suggested that Sodium Oxybate should be available for a small subgroup of patients. The committee discussed the comment and felt that such a request would fall within the IFR process where a request can be made for use in an exceptional patient group. The committee considered the evidence, safety, risk of abuse, side effects and cost-effectiveness data associated with the use of Sodium Oxybate. **Decision** The committee agreed with the recommendation of a Black colour classification. **Action** Sodium Oxybate will be put onto the LMMG website as Black colour classification.	
2016/069	**Horizon Scanning – Quarter 1 2016/17** BH discussed the medicines expected to be launched or have a licence extension during the first quarter 2016/17. Ticagrelor – Cardiovascular disease – there is a license extension for secondary prevention post-MI – extended use. The committee agreed that this will be added to the work plan pending receipt of a completed application form; MLCSU will contact specialists to request that an application form is completed specifying that patient group, estimated cost impact etc.	**BH**

	Ferric Maltol – Anaemia – the committee agreed that this was not a high priority area and will not be added to the work plan. Lesinurad – Gout – NICE guidance is due in November 2016; the committee agreed that this will not be reviewed in light of the impending publication of the NICE TA. The committee agreed that the following medicines would not be reviewed as they fall outside of LMMG's remit: Ceftazidime + avibactam – Bacterial infections Ceftazidime + avibactam – Urinary tract infection Dapagliflozin + saxagliptin – Type II diabetes mellitus	
2016/070	**LMMG – New Medicines Reviews Work Plan update** DP discussed this paper; updating the committee on the current status of the work plan as follows: *Medications recommendations for May LMMG* Second line use of biologics – Crohns – currently out to consultation. Second line use of biologics – Ulcerative Colitis – currently out to consultation. Ulipristal (Esmya) – Uterine Fibroids – currently out to consultation. Liothyronine – persisting lethargy despite levothyroxine replacement/Thyroid cancer awaiting ablative treatment – currently out to consultation. *Medications recommendations for June LMMG* Biologics pathway – Psoriasis – a Lancashire pathway based on the GMMMG pathway will be developed and a clear place in therapy defined. Guanfacine – ADHD *Medications for future reviews* Tapentadol prolonged release – Severe chronic pain Albiglutide/Dulaglutide – Diabetes Lurasidone – Schizophrenia – the committee agreed that this is a high priority. Eluxadoline – Irritable bowel syndrome – diarrhoea predominant Infliximab – Pyoderma Gangrenosum Colesevelam – Familial hypercholesterolaemia *New Medicine Reviews – on hold awaiting licensing and launch* Naltrexone/bupropion – Obesity Bazedoxifene/conjugated oestrogen – post menopausal osteoporosis + menopausal symptoms Safinamide – Mild-late stage Parkinson's disease Liraglutide – Obesity	**All actions DP**

GUIDELINES and INFORMATION LEAFLETS		
2016/071	**Rheumatoid Arthritis Biologics Pathway – update** SM presented this paper which has been updated following the publication of NICE TA375. SM informed LMMG members that the Rheumatology Alliance has approved the updates. It was noted that the pathway will be reviewed further by the Alliance, with consideration of Etanercept biosimilar and brought to a future LMMG for discussion. **Decision** The committee approved the amendments made to the RA Biologics Pathway. **Action** The RA Biologics Pathway will be uploaded to the website.	**SM**
2017/072	**Assessment of Trans-Anal Irrigation Devices and Position Statement** SM discussed this paper which outlined that subsequent to the transanal irrigation systems evidence review conducted by LMMG in June 2015, the LMMG process for device review has been updated. As a consequence, further information was provided from local specialists and manufacturers around safety in use and the place in therapy of each device. The recommendations made at the June LMMG (below) were discussed and considered in line with the information contained within this paper as follows: **Neurogenic bowel dysfunction (NBD)** June 2015; *Peristeen*® was recommended for use in NBD in patients who have exhausted all other conservative treatment options (Amber 1 colour classification) *Qufora® and Aquaflush®* for NBD was not supported due to a lack of robust safety information pending further discussions with the specialist services (grey colour classification) The committee considered all the effectiveness and safety information supplied by the manufacturers and clinicians and agreed that the Qufora® range and the IryPump® will be added to the recommendation for use in neurogenic bowel dysfunction in patients who have exhausted all other conservative treatment options. The website will be updated to reflect this. The committee were not able to make a recommendation regarding the use of Aquaflush® because; there was insufficient	

	published evidence, safety information was not provided by the manufacturers and the specialist teams did not consider it to offer any additional benefits over alternative devices. **Chronic constipation or chronic faecal incontinence** June 2015; *Use of trans-anal irrigation systems/rectal irrigation systems* for chronic constipation or chronic faecal incontinence was not recommended. The committee considered the local audit data provided by Lancashire Teaching Hospitals. Declarations of interest from DS were noted. The committee noted that if use of transanal irrigation systems were extended to these indications, it would potentially result in a significant increase in prescribing. The committee further noted that the associated commissioning pathways had not been agreed in all areas and were concerned that patient follow-up could impact on primary care resources. It was agreed that a decision would be deferred until CCGs had further considered and agreed the associated commissioning pathway. CCGs will feedback regarding their commissioning position. The LMMG website will be changed from Black to Grey colour classification. Arrangements for existing patients are to remain unchanged **Actions** The LMMG website will be updated to include Peristeen®, Qufora® range and the IryPump® for NBD and these will be made Amber 0 on the website. Use of trans-anal irrigation systems/rectal irrigation systems for chronic constipation or chronic faecal incontinence will be changed from Black to Grey colour classification on the LMMG website. The position statement will be updated to reflect the decisions made above. CCGs MM Leads to feedback on their commissioning position for Use of trans-anal irrigation systems/rectal irrigation systems for Chronic constipation or chronic faecal incontinence Once feedback from all CCG MM Leads has been received by MLCSU, SM will write to other areas confirming the Lancashire position.	**SM** **SM** **SM** **CCG MM Leads** **SM**
2017/073	**Constipation Guideline – Scoping document** SM discussed the scoping document.	

	Responses from 3 CCGs and 3 provider Trusts were received. 4 were in favour of the development of a Constipation guideline and 2 were not. An additional comment has been received from BTH supporting the development of the guideline with a request to incorporate guidance around specialist treatments initiated in secondary care. It was agreed that a simple treatment algorithm will be developed. **Decision** The committee agreed on the development of a Constipation Guideline. **Action** The Constipation Guideline will be added to the work plan.	**SM**
2017/074	**Erectile Dysfunction Guideline – Update** SM presented this paper which had been updated in light of the recommendation at the March 2016 LMMG to classify Tadalafil Daily tablets as Red when supplied through specialist sexual health services for specific patients groups only. The committee also considered the role of tadalafil daily post-prostatectomy, in the context of the evidence outlined in the LMMG clinical guidance. It was noted that the majority of the evidence in support of PDE5 inhibitors post prostatectomy related to sildenafil and it was agreed that this should be clarified as the first line PDE5 inhibitor post prostatectomy. The committee further agreed that there was insufficient evidence to support the use of tadalafil daily post prostatectomy in preference to alternative routinely commissioned PDE5 inhibitors. **Decisions** The word "psychosexual" will be removed from the box at the bottom of 4.2 to read: *Assess therapeutic outcome and use of treatment* If unsatisfactory response refer to specialist services. Section 4.4 will be updated to reflect that: • Sildenafil daily is the first line PDE5 inhibitor post prostatectomy • Tadalafil daily is not recommended but tadalafil on demand may be used as a second line PDE 5 inhibitor The committee approved the amendments made to the guidance. **Action** The Erectile Dysfunction guideline will be uploaded to the LMMG	**SM**

	website**.** Tadalafil post prostatectomy will be put onto the LMMG website as Black colour classification.	
2017/075	**Colour Classification Review, List 1 – outstanding actions** Following the initial discussions at the February 2016 LMMG, SM discussed the outstanding comments in this paper as follows: *LMWHs for patients on VTE including therapy* The committee agreed to defer this item until clarification is provided by PB regarding recharging of costs to NHS England for the supply of LMWH for patients on VTE inducing chemotherapy. *Denosumab for therapy induced bone loss, in non-metastatic prostate cancer* The committee agreed that this will be removed from the LMMG website in light of NICE CG175 which had superseded NICE TA194. Should specialist wish to use Denosumab for this indication, a new drug application should be submitted to LMMG for consideration. *Dutasteride for benign Prostatic Hyperplasia* The committee agreed that this will remain on the LMMG website at Amber0 colour classification. SM will contact Urologists for their views regarding its place in therapy and supporting evidence. *Dutasteride/Tamsulosin (Combodart®)* The committee agreed that this will remain on the LMMG website as Amber0 colour classification. SM will contact Urologists for their views regarding its place in therapy and supporting evidence.	**PB** **All Actions SM**
2017/076	**LMMG – Guidelines Work Plan update** SM discussed this paper; updating LMMG on the current status of the work plan, as follows: *Out to consultation* Best practice guideline for ordering and supply of continence and stoma produces – this will be discussed at the May LMMG. Colour Classifications Review List 2, BNF Chapters 1, 10 & 13 – this will be discussed at the May LMMG. *In development* Patient information Leaflets, Riluzole, Vitamin D and Clopidogrel – these have been reformatted for consistency and will be sent out to consultation shortly.	

	Mycophenolate Shared Care Guidance (Unlicensed indications) – further work is required around the indications which are suitable for shared care. Toujeo Insulin – Information Sheet- this was requested in order to address concerns around dosing and selection errors. <u>*New Additions – work to start soon*</u> Neuropathic Pain, Patient Information Leaflet - agreed for incorporation into the neuropathic pain guidance. Melatonin, Position Statement/Guidance – it was agreed that a working group would be established to fully consider the wider complexities of local patient pathways and use. Oral Anticoagulation Prescribing Guide – it has been agreed that 3 individual documents, relevant to prescribing oral anticoagulants in AF should be amalgamated and information about warfarin incorporated. <u>*Other LMMG work*</u> Co-Trimoxazole Shared Care Guideline – currently on hold, awaiting feedback from secondary care regarding management of abnormal blood results. The committee agreed that this will be made Red for new patients on the LMMG website, until such time a shared care guideline has been agreed. Apomorphine Shared Care Guideline – LMMG comments have been feedback to LTHTR, but no response has been received to date The committee agreed that this will be made Red for new patients on the LMMG website, until such time a shared care guideline has been agreed. Palliative Care Prescribing Guideline – on hold, Awaiting further feedback from SCN regarding the future format of the guidelines and geographical area that they will cover. . The areas below were discussed by the committee and actions agreed as follows: <u>Mycophenolate Shared Care Guidance</u> SM will circulate the evidence for use of mycophenolate in rheumatoid arthritis, psoriatic arthritis and systemic lupus erythematosus, and consult on the colour classification of mycophenolate for these indications. This will be put onto the website as Grey Colour Classification. SM to liaise with University Hospital of South Manchester regarding use of mycophenolate in ILD.	**All actions SM**

	Complex pain syndrome will added to the website as Red colour classification – only for use in the context of a clinical trial. Should specialists wish to use mycophenolate for wider indications, it was agreed that there was a requirement for them to submit the evidence in support of use. <u>Zero Risk Schemes in Advance of NICE.</u> SM discussed zero risk schemes and outlined the surrounding concerns. The committee agreed that a Lancashire wide Position Statement will be developed to provide clarity and promote consistency across Lancashire. This will be added to the work plan. For information SM highlighted information attached an Appendix 2 Early access to Medicines Scheme for 'Sacubitril/Valsartan.' <u>Inhaler Comparison and Identification Guide</u> A suggestion for the development of an inhaler comparison and identification guide for asthma and COPD was discussed. The committee agreed that this will be added to the work plan. JL will forward a MIMS document to SM to use as a starting point.	**JL**
NATIONAL DECISIONS FOR IMPLEMENTATION		
2016/077	**New NICE Technology Appraisal Guidance for Medicines (March 2016)** SM presented this paper, the following actions were agreed: TA386 Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis – this is an NHS England commissioning responsibility and will be added to the website at Red colour classification. TA23 Guidance on the use of emozolomide for the treatment of recurrent malignant glioma (brain cancer) – this is an NHS England commissioning responsibility and will be added to the website as Red colour classification.	**All actions SM**
2016/078	**New NHS England medicines commissioning policies (January, February & March 2016)** BH highlighted information in the following NHS England commissioning policies: <u>Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer</u> For information, following a review of evidence from two trials published late last year, specialists will now be able to prescribe the chemotherapy drug docetaxel as soon as someone is diagnosed with incurable prostate cancer.	

	<u>NHS England – Patient safety alert – Risk of severe harm or death when desmopressin is omitted or delayed in patients with cranial diabetes insipidus</u> For secondary care information, following reports of patient safety incidents caused by an omission or delay in the provision of desmopressin, providers of NHS care are asked to consider if immediate action needs to be taken locally to raise awareness and reduce the risk of these incidents from occurring. <u>Changes in medicines legislation for dieticians, orthoptists and radiographers</u> For information, the changes to legislation will introduce independent prescribing responsibilities for Therapeutic Radiographers and supplementary prescribing responsibilities for Dieticians. They will also enable Orthoptists to supply and administer medicines under exemptions within Human Medicines Regulations. <u>NHS England launches national programme to combat antibiotic over usage</u> For information, the programme will offer hospitals incentive funding worth up to £150 million to support expert pharmacists and clinicians review and reduce inappropriate prescribing.	
2016/079	**Evidence reviews published by SMC or AWMSG (February & March 2016)** DP discussed the SMC and AWMSG recommendations published during February and March 2016 meeting LMMG criteria, which were: <u>SMC</u> <u>February 2016</u> 1123/16 Guanfacine (Intuniv®) SMC accepted Guanfacine (Intuniv®) for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. This has been added to the work plan. 1128/16 Ulipristal acetate (Esmya®) SMC accepted Ulipristal acetate (Esmya®) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This has been added to the work plan. <u>March 2016</u> 1126/16 Insulin detemir (Levemir®) SMC accepted Insulin detemir (Levemir®) for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. The NICE Bites evidence review will be looked at. Following this, a decision whether to add this to the work plan will be made.	**DP**

	1127/16 Oseltamivir (Tamiflu®) SMC accepted Oseltamivir (Tamiflu®) for the treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. The committee decided that no action will be taken; PH guidance is awaited. 1132/16 sacubitril/valsartan (Entresto®) SMC accepted Sacubitril/valsartan (Entresto®) for the treatment of symptomatic chronic heart failure with reduced ejection fraction in adult patients. The information was highlighted to the committee under Zero Risk Schemes in Advance of NICE. It was discussed that the remaining SMC and AWMSG recommendation for February and March 2016 did not meet LMMG criteria; therefore the committee agreed that no further action would be taken with regard to them.	
ITEMS FOR INFORMATION		
2016/080	**Minutes of the Lancashire Care FT Drug and Therapeutic Committee (15th March 2016)** The committee noted these minutes.	
2016/081	**Minutes of the Lancashire CCG Network (25th February 2016)** The committee noted these minutes.	

Date and time of the next meeting
12th May 2016, 9.30 am to 11.30 am, Meeting Room 253, Preston Business Centre

ACTION SHEET FROM THE
LANCASHIRE MEDICINES MANAGEMENT GROUP
14th April 2016

MINUTE NUMBER	DESCRIPTION	ACTION	DATE	STATUS AT 14.04.2016
ACTION SHEET FROM THE 11th FEBRUARY 2016 MEETING				
2016/028	**Horizon Scanning 2016/17 Financial Year** 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:** BH will follow this up with JK via email. MP will forward similar information following a meeting with Leads at Blackpool. BH will forward this to the committee and engage with PH. 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 comments have been received; BH asked for feedback of priority areas to be sent to MLCSU as soon as possible.	**JK/MP/BH** **Secondary Care MM Leads**	**05.05.2016** **05.05.2016**	**Open** **Open**
ACTION SHEET FORM THE 10TH 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. **Update:** The information has been received and a draft document has been produced.	**DJ**	**07.04.2016**	**Closed**
2016/056	**LMMG – guidelines Work Plan update** Decision Aid for Antivirals During Flu outbreaks **Action:** SM will contact PH to raise concerns around a lack of up to date diagnosis and treatment pathway. **Update:** A draft has been produced and will be sent to PHE shortly	**SM**	**05.05.2016**	**Open**

ACTION SHEET FROM THE MEETING 14th APRIL 2016				
2016/072	**Assessment of Trans-Anal Irrigation Devices and Position Statement** **Use of transanal irrigation systems/rectal irrigation systems for chronic constipation or chronic faecal incontinence** **Action:** CCGs to feedback their commissioning position. **Action:** Once CCG feedback has been received by MLCSU, SM will write to other areas clarifying the current Lancashire position.	**CCG MM Leads** **SM**	**05.05.2016** **05.05.2016**	**Open** **Open**
2016/075	**Colour Classification Review – List 1 outstanding actions** **LMWHs for patients on VTE including therapy** **Action:** PB will feedback once clarification has been received regarding the recharging of LMWH costs to NHS England for patients on VTE inducing chemotherapy. **Dutasteride for benign Prostatic Hyperplasia & Dutasteride/Tamsulosin (Combodart®)** **Action:** SM will contact Urologists for clarification of its place in therapy for use in patients with enlarged prostate.	**PB** **SM**	**05.05.2016** **05.05.2016**	**Open** **Open**
2016/076	**LMMG – Guidelines Work Plan update** **Mycophenolate Shared Care Guidance** **Action:** SM will liaise with UHSM regarding use of use of mycophenolate for ILD. **Inhaler comparison and identification guide** **Action**: JL will forward a visual guide to inhalers produced by MIMS for information.	**SM** **JL**	**05.05.16** **05.05.2016**	**Open** **Open**