



**Minutes of the Lancashire Medicines Management Board Meeting
held on Thursday 15th November at Preston Business Centre**

PRESENT:

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| Dr Tony Naughton (TN) | Chair | Fylde & Wyre CCG |
| Catherine Harding (CH) | Head of Medicines Management | NHS East Lancashire |
| Elaine Johnstone (EJ) | Associate Director of Medicines Management | NHS Central Lancashire |
| Louise Winstanley (LW) | CCG Lead Pharmacist and Prescribing Support Team Manager | Fylde and Wyre CCG |
| Julie Lonsdale (JL) | Head of Medicine Management | NHS North Lancashire |
| Brent Horrell (BH) | Assoc. Head of Med Management | NHS Central Lancashire |
| Pauline Bourne (PB) | Senior Pharmacist Medicines Management | University Hospitals of Morecambe Bay |
| Dr Robert Mitchell (RM) | Clinical Lead & Board Member | Fylde & Wyre CCG |
| Dr Kamlesh Sidhu (KS) | GP Prescribing Lead | North Lancs CCG |
| David Jones (DJ) | Acting Chief Pharmacist | Lancashire Teaching Hospitals NHS Foundation Trust |
| Dr Sakthi Karunanithi (SK) | Dir of Population Health Care/ Public Health Lancashire | Lancashire County Council |
| Mark Collins (MC) | Dir of Operations | Pharmacy Pennine Lancashire (Local Pharmaceutical Committee) |
| Sonia Ramdour (SL) | Lead Pharmacist | Lancashire Care NHS Foundation Trust |
| Cath Lawless (CL) | Admin Support | NHS Blackburn with Darwen |

ACTION

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| 1. | WELCOME AND INTRODUCTIONS Dr Naughton, Chair of the Fylde and Wyre CCG and nominated Chair of the Lancashire Medicines Management Board on behalf of the Lancashire CCG Network welcomed attendees to the meeting and asked for all organisations to send a representative to the meetings if they are unable to attend. | |
| 2. | APOLOGIES Apologies were received from: Dr Jim Gardner, Neil Fletcher, Melanie Preston, Lisa Rogan, Dr Catherine Fewster (Sonia Ramdour representing), Lindsay Holden, Alastair Gibson, Dr David Shakespeare, Dr Thomas Mackenzie, Dr Muzaffar, Dr Amanda Doyle, Dr Jane Lofthouse, Dr Li Kam Wa | |
| 3. | DECLARATIONS OF INTEREST PERTINENT TO THE AGENDA There were no declarations of interest. | |
| 4. | DECLARATION OF ANY OTHER URGENT BUSINESS PB asked for a matter of urgent business to be deferred until the next meeting. | |
| 5. | MINUTES OF THE MEETING HELD ON 4TH OCTOBER. | |

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| | <p>Where accepted as a true and accurate copy with the exception of: Page 1 Apologies – Should read Dr Manjit Jandu Present - To include David Jones and Dr Jane Lofthouse Page 5 Incorrect spelling of Valvular</p> | |
| 6. | <p>MATTERS ARISING:</p> <p>Terms of Reference Action sheet from 4th October – Terms of Reference Page 1 CH reported that the draft TOR have been updated with amendments being in red type.</p> <p>Page 1 Core Business Included MHRA Drug Safety Updates highlighted in red.</p> <p>Page 2 Sub Groups Added Lancashire HIV Formulary Group</p> <p>Page 3 Members should: Added to <i>review the agenda and supporting papers in advance of the meeting</i> and added a <i>clause around confidentiality</i>.</p> <p>Decision Making: Added content of which to be considered and agreed by the Medicines Management Board. Added voting will be on the basis of one vote per organisation with the Chair having the casting vote. Reference to reporting arrangements through the PCT Cluster Board had been removed.</p> <p>Further Comments: SK asked for there also to be added and considered recommendations from the Joint Pharmaceutical Needs Assessment Partnership.</p> <p> Lancashire Medicines Management Board T</p> <p>LW suggested that discussion of the draft Terms of Reference be deferred pending further discussion to include absent members of the group whom she felt would be able to add to the discussion. A lengthy discussion was had on the governance arrangements for the Board in respect of processes for reaching decisions and making recommendations, particularly in respect of CCGs. In summary it was agreed that there needed to be more clarity on how recommendations would be ratified within individual organisational governance arrangements. EJ said that local arrangements would sit outside this group.</p> <p>Draft Over-arching policy / procedure for the Lancashire MMB A draft overarching policy document for the priority setting of medicines and operation of the Lancashire Medicines Management Board was presented by CH. The document was based on a model policy currently operating in Pennine Lancashire that had been revised and updated to make it relevant to CCGs and the Lancashire Medicines Management Board. It was suggested that reference to the NHS Constitution be included. SK highlighted the similarity with the Individual Patient Activity / Individual Funding Request work and the importance of it being aligned. The Lancashire Principles for the Commissioning of Health and Healthcare developed with leadership from public health were included in Appendix 2 of the policy. It was suggested that</p> | |

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| | <p>Appendix 2 should be specifically referenced as the Ethical Framework.</p> <p>In view of a number of organisations not being represented at the meeting the Chair suggested that members be provided with further opportunity to comment on the draft policy before presenting the policy and group Terms of Reference for consideration by the meeting of the Lancashire CCG Network on the 20th December.</p> <p>ACTION: Members to forward further comments on the Terms of Reference and policy document to Catherine Harding by the 29th November prior to further consideration by the Lancashire CCG Network at its meeting on the 20th December.</p> <p>To Note: MC joined the meeting</p> | ALL |
| 7. | <p>Sub Group Terms of reference – Presented by Catherine Harding – Draft Terms of Reference for the New Medicines and Treatments and NICE sub-groups were presented by CH.</p> <p>LW proposed that a task and finish group should be set up to look at the Terms of Reference and policy document at a CCG level. BH expressed his concern that clarity was required on how CCG's would consider and act on recommendations from the Lancashire Medicines Management Board. TN indicated that he had spoken with the Chair of the Lancashire CCG Network, Dr Chris Clayton (BWD CCG) at length who provided him with assurance that the Lancashire MMB has the support of the Lancashire CCG Network.</p> <p>ACTION: As a CCG representative, LW to organise and lead on a task and finish group inclusive of CCG clinical members to provide CCG leadership in the development of a transition plan outlining the necessary actions and processes required to enable a collaborative Lancashire commissioner approach to medicines prioritisation and decision making in the new system. The outputs from this work would be taken to the Lancashire CCG Network for consideration.</p> | LW |
| 8. | <p>Cardiac & Stroke Networks and medicine management collaborative processes – Deferred. To be considered in the broader discussion on the Board Terms of Reference and those of its sub-groups.</p> | |
| 9. | <p>High Cost drugs – Update paper to Lancashire MMB – Presented by Catherine Harding A report prepared by Richard Lee and Diane Eden from the Cumbria and Lancashire NHS Collaborative Business Services was presented by CH. At present it is estimated that £46.5 million is being spent by Lancashire and Cumbria PCTs on high cost drugs, with anti-TNF drugs being one of the largest areas of spend. From April 2013 CCGs will be responsible for the commissioning and funding of those high cost drugs used within services and treatment pathways commissioned by CCGs.</p> <p>High cost drugs had been a collaborative commissioning workstream and the</p> | |

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| | <p>report provided an update on progress and achievements to date. CH highlighted the recommendations and what was being asked of the Lancashire MMB.</p> <p>The Board agreed to:</p> <ul style="list-style-type: none"> • support and oversee a continued collaborative approach to the commissioning and use of high cost drugs and homecare medicines as an already established QIPP workstream • (with reference to the role of the Lancashire MMB in formulating recommendations for the use of medicines across Lancashire and further discussion as per items 6 and 7) act as the forum for consensus decision making in relation to policies or proposals for high cost drugs and homecare medicines, making recommendations to CCGs and providers for their use <p>The on-going work with the rheumatologists to agree common treatment pathways for the use of the anti-TNFs and proposed agenda for a meeting of the Rheumatology Alliance and medicines management representatives to be held on the 23rd November were noted.</p> <p>ACTION: Richard Lee to be asked to provide an update report to a future meeting of the Lancashire MMB on this programme of work. Proposed commissioning policies for the use of anti-TNFs in rheumatology treatment pathways recommended by the Rheumatology Alliance and medicines management to be considered by the Lancashire MMB as they are developed.</p> | <p>RL</p> |
| <p>10.</p> | <p>Horizon Scanning Briefing Report: Presented by Elaine Johnstone EJ presented the briefing report and asked for the information not to be shared any wider as the report included confidential information – namely it highlights medicines that are expected to be launched during 2013/2014 as well as new indications for established medicines that are likely to have a significant impact for CCGs. The report excluded those medicines known to be commissioned by the NHS CB in future i.e. chemotherapy.</p> <p>Members of the group sought clarity on the methodology for determining the priority score and the desire for more detailed financial information to assess financial impact. It was noted that this was an early version of the report pending the release of financial information nationally, at which point it would be updated. The population figures needed amending to reflect CCG populations rather than PCT.</p> <p>It was agreed that the New Medicines and Treatments working group should be asked to utilise the horizon scanning report as a basis for prioritising a programme of work, making recommendations to the Lancashire MMB for consideration.</p> <p>ACTION: New Medicines and Treatments sub-group to be asked to formulate a prioritised work programme, to proactively consider new medicines coming to market and new indications for existing medicines prior to launch.</p> | <p>EJ</p> |

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| 11. | <p>Aflibercept (Eylea®) Briefing Report – Presented by Elaine Johnstone A report prepared by Richard Lee was presented by EJ. A new treatment for AMD (aflibercept) is expected to receive a UK marketing authorisation in December 2012. Its utilisation within the treatment pathway for AMD in suitable patients has the potential to release savings and provider capacity across the NHS in Lancashire. Aflibercept has not at present been considered by NICE and there is an opportunity for a local decision to be taken. The Lancashire MMB was asked to endorse a dialogue with ophthalmologists on behalf of CCGs to develop a clinical pathway including aflibercept as a treatment option for wet AMD, and this was supported.</p> <p>ACTION: Task and finish group working with ophthalmologists to be established to review the evidence for aflibercept and make recommendations to the Lancashire MMB. New Medicines and Treatments Group to oversee the programme of work.</p> | EJ |
| 12. | <p>Fingolimod (▼Gilenya®) for the treatment of multiple sclerosis– Presented by Brent Horrell BH briefed the group on the position statement for the use of Fingolimod. Fingolimod is licensed as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:</p> <p>- Patients with high disease activity despite treatment with a beta-interferon. These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least 1 relapse in the previous year while on therapy, and have at least 9 T2-hyperintense lesions in cranial MRI or at least 1 Gadolinium-enhancing lesion. A “non-responder” could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.</p> <p>or</p> <p>- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.</p> <p>Fingolimod is recommended by NICE (TAG 254, April 2012) as an option for the treatment of highly active relapsing–remitting multiple sclerosis in adults, only if:</p> <ul style="list-style-type: none"> • they have an unchanged or increased relapse rate or ongoing severe relapses compared with the previous year despite treatment with beta interferon, and • the manufacturer provides fingolimod with the discount agreed as part of the patient access scheme. <p>NICE has been asked to clarify whether the recommendation for the use of fingolimod extends to people with relapsing remitting multiple sclerosis who are currently receiving treatment with glatiramer acetate, and who experience an unchanged or increased relapse rate or ongoing severe relapses</p> | |

compared with the previous year. NICE understands that this query refers to the note included in the 'Posology and method of administration' section of the summary of product characteristics for fingolimod that states that 'patients can switch directly from beta interferon or glatiramer acetate to fingolimod provided there are no signs of relevant treatment-related abnormalities'. In line with the referral received from the Department of Health, NICE appraised fingolimod with reference to the therapeutic indication specified in the marketing authorisation; that is 'Patients with high disease activity despite treatment with a beta-interferon'. The manufacturer provided no submission for the other population in the marketing authorisation. Considering that NICE cannot produce guidance for a medicine outside of the licensed indication included in the marketing authorisation, the recommendation for the use of fingolimod does not extend to people currently receiving glatiramer acetate.

NICE were unable to make a specific recommendation about the use of fingolimod in patients with rapidly evolving severe (RES) relapsing–remitting multiple sclerosis because the manufacturer had not submitted an analysis of fingolimod compared with natalizumab in this population. NICE acknowledged the clinical specialists' disappointment at this since the clinician view was that fingolimod would provide the greatest benefit to people with rapidly evolving severe relapsing-remitting multiple sclerosis because they currently have very few treatment options.

A position statement for the local commissioning of fingolimod had been developed by Lisa Rogan, Chair of the East Lancashire health economy New Medicines and Treatments Group in consultation with local clinical specialists from Lancashire Teaching Hospitals NHS Trust. The position statement was based on work produced by the Greater Manchester Medicines Management Group's Neuroscience Network. The position statement recommends as a treatment option the use of fingolimod in accordance with NICE guidance for those patients with highly active relapsing-remitting multiple sclerosis who fail on beta-interferon. It also permits the use of fingolimod for those patients with highly active relapsing-remitting multiple sclerosis who fail on glatiramer acetate (out of licence and not considered by NICE), and those patients with RES who are either not suitable for natalizumab or who fail on natalizumab (within licence but not considered by NICE).

Summary of position statement:

- Patients who have rapidly evolving severe (RES) relapsing remitting MS but are not considered suitable for natalizumab (Tysabri[®]) because of the clinical concerns (risk stratification) about the possibility of developing progressive multifocal leukoencephalopathy (PML); or
- Patients who fail on natalizumab (Tysabri[®]) due to neutralising antibodies and, or anaphylactic reaction; or
- Patients who fail on natalizumab (Tysabri[®]) due to relapses; or
- Patients who fail on beta-interferon (Avonex, Betaferon/Extavia, Rebif 22/44) and/or glatiramer acetate (Copaxone[®]) who have had more relapses than the previous year; or
- Patients who fail on a beta-interferon (Avonex, Betaferon/Extavia, Rebif 22/44) and/or glatiramer acetate (Copaxone[®]) due to inability to self-inject, lack of adequate injection sites or skin necrosis; or
- Patients who develop high and sustained levels of neutralising antibodies to a beta-interferon (Avonex, Betaferon/Extavia or Rebif

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| | <p>22/44) and also fail on glatiramer acetate (Copaxone®) due to inability to self-inject, lack of adequate injection sites or skin necrosis.</p> <p>The Board heard that the sub-group of patients using fingolimod was likely to be low and any increased costs would be offset against administration costs associated with natalizumab (for patients with RES). Where fingolimod was to be offered to patients who had failed on glatiramer acetate, the incremental cost per annum across the Lancashire CCGs was in the order of £25,000. (It was noted that the total commissioner annual spend across Lancashire on drug treatments for MS was circa £900,000. The cost implications of implementing the NICE guidance on fingolimod was in the order of £75,000 per annum).</p> <p> Fingolimod position statement October 2012</p> <p>The position statement was supported by the meeting, but LW suggested that CCGs would not approve in the absence of NICE and concluded that the minutes needed to be supplemented by additional information explaining the reasoning for the decision so that CCGs to have confidence in endorsing the recommendations clinically.</p> | |
| 13. | <p>Joint Formulary for Psychotropic Medication – Presented by Sonia Ramdour</p> <p>The joint work of the Lancashire Care Foundation Trust (LCFT) and PCTs across Lancashire in agreeing a joint prescribing formulary for psychotropic medication was presented by Sonia Ramdour, Lead Pharmacist at LCFT and Julie Lonsdale, Head of Medicines Management at North Lancashire PCT. The Lancashire Medicines Management Board was asked to endorse the joint formulary. For clarity, BH suggested that a clarifying statement be included in the formulary introduction explaining that all medicines available for prescribing in the BNF are listed with those medicines not approved for use being indicated as <i>non-formulary</i> or <i>black traffic lighted</i>.</p> <p>Reference was made to shared care prescribing and shared care protocols being poorly agreed with primary care and inadequately shared. SR advised that shared care documents have been agreed by all Lancashire PCTs except for Blackpool and expressed a desire to progress shared care work in Blackpool.</p> <p>To Note: SK left the meeting.</p> <p>Approval was given for the joint formulary – Discussion around the document and where it would sit was discussed as it was agreed that it would be useful to share on a national basis.</p> <p> Joint Formulary -Updated Nov 2012.c</p> | |
| 14. | Shared Care Guidelines for Immunosuppression following Renal | |

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| | <p>CH presented a position statement on the prescribing and supply of herpes zoster vaccine for consideration. It was noted that the Department of Health was considering the introduction of a national herpes zoster immunisation programme in persons aged 70 to 79 years pending an evaluation of the cost-effectiveness. A licensed herpes zoster vaccine is available and prescribable on FP10 on a case by case basis. The estimated cost of implementing a herpes zoster vaccination programme in Lancashire outside of a national immunisation programme was estimated to cost in the region of £13 million. Having sought advice from the HPA, the recommendation was that until the Department of Health announces the introduction of a national herpes zoster immunisation programme, the prescribing and administration of herpes zoster vaccine in primary care in Lancashire could not be supported.</p> <p>The position statement was approved by the Board.</p> <p></p> <p>Recommendations for the prescribing of</p> <p>SK suggested involvement of the HPA in communicating the message to stakeholders as a co-signatory on any correspondence.</p> | |
| | <p>DATE AND TIME OF NEXT MEETING Thursday 13th December 9.30 – 11.30 A.M. Meeting Room 2, Preston Business Centre. link to venue directions http://www.lancsteachinghospitals.nhs.uk/trust-information/find-us/directions-to-smrc.html</p> | |
| | <p>FUTURE MEETINGS</p> <p>Future meeting dates would be scheduled for the 2nd Thursday of the month at 9.30am, to be held in Meeting Room 2, Preston Business Centre.</p> <p>9.30 am – 11.30am (All Thursdays) in Meeting Room 2, Preston Business Centre</p> <p>13th December (2012) 10th January (2013) 14th February (2013) 14th March (2013) 11th April (2013) 9th May (2013) 13th June (2013) 11th July (2013) 8th August (2013) 12th September (2013) 10th October (2013) 14th November (2013) 12th December (2013)</p> | |

**ACTION SHEET FROM THE
LANCASHIRE MEDICINES MANAGEMENT BOARD**

THURSDAY 13th November 2012

| MINUTE NUMBER | DESCRIPTION | ACTION | DATE |
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| 2012/006 | <p>NICE consultation the development and updating of local formularies CH to update the Draft Terms of Reference to address gaps highlighted by the NPC consultation document</p> <p>Operational policy for the Lancashire Medicines Management Board to be drafted and considered at the next meeting</p> | <p>CH</p> <p>CH</p> | <p>Action complete</p> <p>Action complete</p> |
| 2012/007 | <p>Lancashire wide prescribing formulary: progress report and next steps Products from the work of the formulary task group to be circulated to members</p> <p>Options paper for the communication of Lancashire Medicines Management Board decisions to be brought back to a future meeting</p> <p>Terms of Reference for the Lancashire MMB to be updated following discussion and re-circulated</p> <p>Terms of Reference for the sub-groups to be drafted and circulated for comment</p> | <p>BH</p> <p>CH</p> <p>CH</p> <p>CH</p> | <p>Oct 12</p> <p>Dec 12</p> <p>Action complete</p> <p>Action complete</p> |
| 2012/009 | <p>Lancashire HIV prescribing formulary HIV formulary group to be recognised as a sub-group of the Lancashire Medicines Management Board in the edited ToR</p> | <p>CH</p> | <p>Action complete</p> |
| 2012/010 | <p>Guidelines for the management of patients with substance misuse problems on admission to acute care Provider Trusts to consider the adoption and/or adaptation of the guidance for use within their own organisations</p> | <p>Trust Reps</p> | <p>Nov 12</p> |
| 2012/018 | <p>Draft Terms of Reference and Overarching Policy Document Members to forward further comments on the Terms of Reference and policy document to Catherine Harding by the 29th November prior to further consideration by the Lancashire CCG Network at its meeting on the 20th December.</p> | <p>ALL</p> | <p>Nov 12</p> |

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| 2012/019 | Sub group Terms of Reference LW to organise and lead on a task and finish group inclusive of CCG clinical members to provide CCG leadership in the development of a transition plan outlining the necessary actions and processes required to enable a collaborative Lancashire commissioner approach to medicines prioritisation and decision making in the new system. The outputs from this work would be taken to the Lancashire CCG Network for consideration. | LW | December 12 |
| 2012/022 | Horizon scanning briefing report New Medicines and Treatments sub-group to be asked to formulate a prioritised work programme, to proactively consider new medicines coming to market and new indications for existing medicines prior to launch. | EJ | January 13 |
| 2012/023 | Aflibercept briefing report Task and finish group working with ophthalmologists to be established to review the evidence for aflibercept and make recommendations to the Lancashire MMB. New Medicines and Treatments Group to oversee the programme of work. | EJ | December 12 |
| 2012/026 | Shared care guidelines for immunosuppressants following renal transplant DJ to incorporate comments into the final version adopted into practice. | DJ | December 12 |
| 2012/027 | Recommendations for the Prescribing of High Fluoride Toothpaste in Primary Care SR to take the proposal to the LCFT D&T Committee meeting on the 27 th November to consider any implications for LCFT provided community dental services. Arrangements for monitoring the application of the guidance to be queried with the Lancashire Dental Transformation Board | SR CH | November 12 November 12 |