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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 13 October 2015

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Dulaglutide	BROWN 2nd line to exenatide MR when a weekly preparation is required.
Evolocumab	BLACK
Insulin Abasaglar (insulin glargine biosimilar)	GREEN 1st line insulin glargine preparation in all new patients where indicated
Insulin Lantus (insulin glargine)	GREEN 2nd line glargine.
Nivolumab	RED (NHS England commissioned drug)
Pembrolizumab	RED (NHS England commissioned drug)
Ciclosporin Eye Drops	RED
Insulin Toujeo (glargine)	BLACK
Edoxaban	Green as per NICE TA 355for stroke prevention in patients with AF
Ruxolitinib	BLACK (NICE terminated appraisal 356)

Clinical Guidelines

Guideline for the Management of Oral Thrush in Infants and Surface and Ductal Thrush in Lactating Women
Varenicline for Smoking Cessation

Patient Group Directions

Influenza, Fluenz Tetra and Intanza
Extended by one month PGDs for use in Derbyshire only **(**Hepatitis A - Adult, Hepatitis A - Child, Hepatitis A and Typhoid, Hepatitis B - Adult, Hepatitis B - Child, Typhoid, Vitamin K)

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
Dr C Emslie	GP
Dr D Fitzsimons	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Ms J Town	Head of Finance
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair- Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Dr S Taylor	Chair – Drugs and Therapeutic Committee
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Trust	
Mr M Steward	Head of Medicines Management
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Ms S Bassi, Mrs L Hunter, Ms M Simpson and Ms R Sokal.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of conflict of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• CCG commissioned Travel Vaccines PGDs and Vitamin K PGD extension. • Oral contraception after use of ulipristal acetate (ellaOne).	
4.	**MINUTES OF JAPC MEETING HELD ON 8 SEPTEMBER 2015**	
	The minutes of the meeting held on 8th September 2015 were agreed as a correct record after the following amendment: Matters arising: Cabergoline and Quinagolide - Mr Dhadli reported that, following discussion with Dr R Stanworth, it had been agreed that cabergoline and quinagolide should have a traffic light classification of GREEN after consultant initiation for the treatment of hyperprolactinaemia.	
5.	**MATTERS ARISING**	
a.	**Learning Difficulties – Winterbourne Medicines Programme** Dr Mott advised that the Learning Disabilities Team based at Hardwick CCG would now take responsibility for the development of the response to the Winterbourne Medicines Programme.	
b.	**Midodrine (Bramox)** Mr Dhadli stated that the number of patients being treated with midodrine for orthostatic hypotension had been obtained from CRHFT and were now awaited from DTHFT. Dr Goddard advised that midodrine would be discussed at the November DTHFT Drugs and Therapeutic Committee meeting. It was agreed that JAPC would discuss whether the current traffic light classification of RED was appropriate at the meeting in December when details of patient numbers had been obtained from both Acute Trusts.	**SD**
c.	**Dulaglutide** Mr Dhadli stated that at the September meeting JAPC had agreed to defer a decision on the traffic light classification of dulaglutide which was a long acting once-weekly Glucagon-like peptide-1 (GLP1) agonist for the treatment of type 2 diabetes. This would allow time for Dr Game, DTHFT Consultant Diabetologist, to be contacted to ascertain her views and also to look at the cost-effectiveness data for liraglutide 1.8mg in the NICE technology appraisal. Mr Dhadli advised JAPC that an incremental analysis of the cost effectiveness of liraglutide 1.8 mg in relation to 1.2 mg had produced results which were significantly different depending on the clinical trial chosen. The 1860 trial analysis had given an ICER of £11,414 per QALY gained for liraglutide 1.8 mg compared with 1.2 mg. However the analysis based on the LEAD-2 study, where the clinical-effectiveness results for liraglutide 1.2 mg and liraglutide 1.8 mg were similar, the cost per QALY gained for 1.8 mg compared with 1.2 mg increased to £249,494. Therefore liraglutide 1.8mg was not considered to be a cost effective option and may be less effective than the 1.2mg formulation. Dr Game had advised that a traffic light classification of BROWN should be assigned.	

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	Agreed: Dulaglutide classified as a **BROWN 2nd line** weekly drug to exenatide MR with exceptionality for those patients who preferred to administer weekly or required administration by a healthcare professional rather than the once or twice daily dosing of some other GLP-1 receptor agonists.	**SD**
d.	**Gain Sharing Principles** Mr Dhadli referred to the document 'Principles for sharing the benefits associated with more efficient use of medicines not reimbursed through national tariff prices' and highlighted the change which had now been made in the CCGs additional criteria section to read: 'Any efficiencies made on high cost medicines, after adjustment for the administrative burden, will be shared between provider and commissioner organisations and utilised in line with the relevant organisation's transformation strategies.' Mr Newman commented that in connection with the bullet point in the same section 'Schemes must not be linked to medicines that are part of clinical trials' a reference should be made to the Cancer Drugs Fund. It was agreed that this would be added as an additional bullet point.	**SD**
	Agreed: The Gain Sharing Principles document was ratified by JAPC with the agreed amendments.	**SD**
e.	**Cabergoline Doses for Parkinson's Disease** Mr Dhadli referred to the query which had been raised whether the 2mg dose of cabergoline was being prescribed for Parkinson's Disease and highlighted that the shared care agreement referred to the use of cabergoline for the treatment of hyperprolactinaemia only. The use of cabergoline for any other indication needed to be recorded and the maximum ceiling dose noted. It was agreed that the North and South Prescribing Groups should look further at the prescribing and the prescribing guideline discussed again by JAPC if any changes were needed.	**SH/KN**
6.	**CLINICAL GUIDELINES**	
a.	**Guideline for the Management of Oral Thrush in Infants and Surface and Ductal Thrush in Lactating Women** Mr Dhadli reported that the clinical guideline for the prescribing for oral thrush in babies and for surface and ductal thrush in lactating women had now been reduced in length and made more practicable as requested by JAPC at the August 2015 meeting. The Guideline Group had made further suggestions to JAPC to: • Provide clarification about length of treatment. • Remove the reference to the 'black swan' tube and that swabs should be sent to microbiology. In addition, a change had now been made to the flucloxacillin dose which should be for fourteen days in line with current guidance. In accordance with the NICE Clinical Knowledge Summary on Breastfeeding Problems, it was now recommended that topical treatment should be continued for at least seven days and for two days after symptoms had been resolved. In the event that the infection had not resolved after seven days, the course of miconazole oral gel should be extended for a further week.	

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	Mrs Needham requested that the reference in the background section to an appropriately person trained and skilled in breastfeeding management to observe a breastfeed to ensure that poor attachment is not causing the problem should be an appropriately trained person. A review date of two years would also be added.	**SD**
	Agreed: JAPC ratified the guideline for the Management of Oral Thrush in Infants and Surface and Ductal Thrush in Lactating Women with the agreed amendments.	**SD**
b.	**Varenicline** Mr Dhadli reported that changes had been made to the guideline in order to take into account the latest research on the prescribing of varenicline for patients with serious mental illness and the risks of cardiovascular disease associated with its use. In addition a number of appropriate references had also been included. It was suggested that, in view of the fact that there were different providers of smoking cessation services, the title of the guideline should be amended to reflect that it applied to all the Derbyshire public health commissioned services for smoking cessation. A review date of two years would also be added.	**SD**
	Agreed: JAPC ratified the varenicline guideline with the agreed amendment.	**SD**
7.	**PATIENT GROUP DIRECTIONS**	
a.	**Fluenz Tetra and Intanza** The Public Health England/NHS England Patient Group Directions for influenza, Influenza (as Fluenz Tetra) and Influenza (as Intanza) were noted by JAPC.	**SD**
	Agreed: JAPC agreed the PGDs for influenza, Fluenz Tetra and Intanza would be added to the medicines management website.	
b.	**Derbyshire Only PGDs** Mr Dhadli advised that the following PGDs for use in Derbyshire only were due to expire at the end of October 2015: • Hepatitis A (Adult) • Hepatitis A (Child) • Hepatitis A and Typhoid • Hepatitis B (Adult) • Hepatitis B (Child) • Typhoid • Vitamin K The Guideline Group had requested that these PGDs be extended by one month to the end of November 2015 in order to allow time for them to be updated.	
	Agreed: JAPC agreed to extend the PGDs for Derbyshire use to 30th November 2015.	**SD**

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8.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli highlighted the following from the Monthly Horizon Scan: Cangrelor for reduction of thrombotic cardiovascular events in patients with coronary artery disease undergoing PCI - Already classified as **BLACK** as per NICE TA 351. Evolocumab for the treatment of mixed dyslipidaemia and homozygous familial hypercholesterolaemia). Evolocumab was administered by subcutaneous injection and a NICE TA was expected in April 2016 – Classified as **BLACK** due to lack of evidence and lack of data on cost-effectiveness. Insulin glargine biosimilar (Abasaglar) – Classified as **GREEN 1st line** for all new patients with recommendation not to switch until more information was gained from the use of the drug. Insulin glargine (Lantus) – Classified as **GREEN 2nd line** Nivolumab – Classified as **RED** (NHS England). Pembrolizumab – Classified as **RED** (NHS England). Ciclosporin eye drops – Classified as **RED** and await clinician request. Insulin glargine injection (Toujeo) – Classified as **BLACK** at launch and await requests via Drug and Therapeutic Committees.	**SD** **SD** **SD** **SD** **SD** **SD** **SD** **SD**
9.	**MISCELLANEOUS**	
a.	**Early Acess to Medicines** Mr Dhadli advised the early access to medicines scheme (EAMS) aimed to give patients with life threatening or seriously debilitating conditions access to medicines that did not yet have a marketing authorisation when there was a clear unmet medical need. Step1 of the EAMS was to gain designation as a Promising Innovative Medicine (PIM) from the Medicines and Health Products Regulatory Authority which would be issued after MHRA had assessed the non-clinical and clinical data available on the product within a defined disease. The MHRA had made resources available to support prescribers and the scheme was voluntary as the opinion from MHRA did not replace the normal licensing mechanism for medicines. The following criteria needed to apply in order to gain a PIM designation: Criterion 1 - The condition should be life-threatening or seriously debilitating with a high unmet need Criterion 2 - The medicinal product was likely to offer major advantage over methods currently used in the UK. Criterion 3 -The potential adverse effects of the medicinal product were likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. Step 2 was a scientific review and Step 3 involved commissioning in the NHS. Mr Dhadli highlighted the following key points concerning EAMS: • Scientific opinion from the MHRA provided the benefit and risk information to doctors who may wish to prescribe the unlicensed medicine under their own responsibility. • Should not be regarded as a medicine licensed by the MHRA or a future commitment by the MHRA to licence such a medicine.	

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	• Healthcare professionals should enrol any patients receiving EAMS medicines in the registry which the pharmaceutical company will have in place to enable systematic collection of information on adverse events. • Prescribing physician requests access for a patient into EAMS and they would receive a set of programme materials from the pharmaceutical company. In the context of EAMS Mr Dhadli informed JAPC that sacubitril/valsartan was a new treatment for adult patients with symptomatic heart failure and reduced left ventricle ejection fraction. These patients typically had a poor prognosis and admissions to hospital were common. The primary composite end point was death from cardiovascular disease or first hospitalisation for worsening heart failure. The trial had ended early because of the overwhelming benefit of sacubitril/valsartan compared to enalapril (10mg BD). The medicine was provided free of charge by the pharmaceutical company until the marketing authorisation was granted. During discussion Mr Hulme queried what the position would be if a licence was not obtained for the drug. Mr Dhadli commented that when EAMS had been developed it had been assumed that the numbers would be small as the drugs concerned would be aimed at those patients with life threatening conditions. However the symptomatic use of sacubitril/valsartan for left ventricular systolic dysfunction (LVSD) could involve a considerable number of patients. Dr Goddard referred to the decision made that all the EAMS drugs should be taken through the DTHFT Drugs and Therapeutic Committee. Mr Shepherd confirmed that this was also the position at CRHFT. Dr Goddard highlighted the need to be cautious about the use of these drugs based on a relatively limited evidence base and, in the case of the drug under discussion, cardiologists may wish to limit the use of it with those patients who had few other options. Dr Mott commented that the trial had been against an active comparator rather than placebo which was not usually the case. However, it was unclear from the available information whether sacubitril/valsartan would be used only for severely ill NHS patients. **Agreed:** A traffic light classification for sacubitril/valsartan would not be assigned at present. **Action:** JAPC would be informed of any requests for EAMS drugs which were submitted via the DTHFT and CRHFT Drugs and Therapeutic Committees.	**WG/MS**
b.	**Excess Treatment Costs** Dr Parkin stated that excess treatment costs (ETCs) for non-commercial clinical trials generally fell into two categories: prescribing and non-prescribing. The prescribing ETCs only had been brought to JAPC for discussion and the non-prescribing ETCs, covering such items as equipment and staffing levels, had been considered by the Derbyshire Research Forum (DRF) which had representation from all the Derbyshire CCGs.	

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	The DRF had decided to liaise with JAPC to ensure that there was no overlap and there was a requirement to fund ETCs if the trials gained approval. It was proposed that the Clinical Research Network (CRN) should have delegated responsibility for this and a paper on this would be taken to the CCG 4 + 4 Group in November. Dr Parkin referred to the process for the ETCs NHS portfolio and non-portfolio trials which involved the CRN Network would assess whether there was a prescribing ETC and, if so, this would be considered by JAPC who would make a recommendation or decision to the CRN. It was anticipated that the CRN would then have the delegated authority to grant approval or not on behalf of the four CCGs taking into consideration cost limitations. Notification would then be conveyed to the relevant Trust or principal investigator.	
	Mr Dhadli reported that the JAPC terms of reference would be amended to reflect that JAPC would advise the Derbyshire Research Forum on non-commercial trials that related to drug excess treatment costs.	**SD**
	Agreed: JAPC ratified the amendment to the JAPC terms of reference.	**SD**
c.	**<u>Lyrica</u>** Mr Dhadli reported that Pfizer had now lost its patent infringement case in the High Court of England and Wales against generic drug manufacturers Actavis and Mylan over the use of pregabalin, marketed as Lyrica. Pfizer's original patent for pregabalin (sold as Lyrica) as a treatment for epilepsy had expired last year and this had enabled Actavis and other manufacturers to launch cheaper branded generic formulations. However, Pfizer had obtained a second-use patent protecting pregabalin as a treatment for pain until July 2017. Pfizer had claimed that the branded generic alternative made by Actavis would inevitably be used to treat pain and therefore infringed on its patent. The ruling may therefore mean that all generic manufacturers could apply for licences for pregabalin for the treatment of pain. Mr Dhadli highlighted that NHS England had indicated that its current advice to doctors to prescribe Lyrica by brand name for use in pain control was still valid and would not change until a court order giving effect to the judgment had been received and the outcome of the appeal by Pfizer was known.	
	During discussion Mrs Needham stated that currently there was no cost difference between prescribing generically or by Lyrica brand in primary care. Dr Mott commented that GP practices would not need to take any action at this point but some decisions would need to be made if the prices of the generics dropped significantly before July 2017.	
	Action: The use of amitriptyline and gabapentin rather than pregabalin for neuropathic pain would be promoted in the newsletter. **Action:** Lyrica would be taken off the action tracker.	**SD** **SD**
d.	**<u>Midlands Therapeutic Reviews and Advisory Committee (MTRAC)</u>** The MTRAC reviews on the insulin glargines, Abasaglar and Toujeo, were noted by JAPC.	

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e.	**Pharmaceutical Price Regulation Scheme Prescribing Growth** Mr Dhadli referred JAPC to the Department of Health Prescribing Price Regulation Scheme (PPRS) 2014 – Analysis of Growth in Spend of Medicines and outlined the main points: • Growth in spend in 2014 (compared to 2013) of 8.2% on branded medicines. The increase is largely driven by the hospital sector (an increase of 16.5%). Community sector spend increased by 1.9% in the same period. • Areas of largest growth are in anti-cancer and rheumatology medicines, wet aged macular degeneration and new oral anticoagulant (NOAC) drugs. Within these therapeutic areas (and across others) a large proportion of the increase in spend is driven by products covered by the Innovation Scorecard. • A single drug, Eylea (Aflibercept), had increased in spend by over £102 million – this was over £50million more than the next highest growth medicine in cash terms which was Lyrica (Pregabalin). Mr Dhadli highlighted that the purpose of the report was to enable CCG commissioners to understand the changing landscape of prescribing and scope where resources could be allocated in the future.	
f.	**Prescribing Specification Consultation** Mr Dhadli outlined the comments which had been received for inclusion in the updated version of the prescribing specification: • Medicines optimisation between Provider Trusts and Commissioners. • Supply of dressings following appointments with community based services and should be broader than day case surgery. • Horizon scanning. • Free of charge schemes and use of biosimilars. • Memorandum of Understanding for co-operative working between NHS England and local CCGs with regard to the safer management of controlled drugs. Mrs Needham suggested that a reference to EAMS should be included in view of the fact that patients attended cross boundary acute providers. Dr Mott stated that a final document would need to have been completed in two months time but in the meantime comments and challenges were needed on the current version in the next two weeks. This would allow sufficient time for discussion and also to gain assurance that all the elements concerning the use of medicines were incorporated as the specification was not just a contractual lever. Mr Newman highlighted a lack of outcomes in the specification in the light of the publication of the NHS Outcomes Framework and medicines optimisation and commented that it would be advantageous to include a reference to how health needs were being met in the specification. Dr Mott commented that it would be difficult to contract specifically for outcomes due to the fact that the specification applied to a variety of providers. Mr Hulme stated that outcomes needed to be part of general discussions in the whole health economy but it should be noted that the specification was part of the contract.	

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	Mr Hulme added that a decision would need to be made as to where to place the outcome measures and referred to discussions which had taken place about the development of a joint medicines optimisation strategy. **Action:** Members were requested to convey any comments on the prescribing specification to Mr Dhadli by 31st October 2015.	**All**
10.	**JAPC BULLETIN**	
	The September JAPC bulletin was ratified.	
11.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Update for September 2015 was noted. Mr Dhadli highlighted the following: • Proton pump inhibitors: very low risk of subacute cutaneous lupus erythematosus. • Yellow Card smartphone app to report suspected adverse drug reactions. • Pseudoephedrine and ephedrine: update on managing risk of misuse.	
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in September 2015: TA 355 Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation – Edoxaban was another option for preventing stroke and systemic embolism in adults with non-valvular atrial fibrillation with one or more risk factors including congestive heart failure, hypertension, diabetes, prior stroke or transient ischaemic attack or age 75 years or older. It was an alternative to rivaroxaban, dabigatran and apixaban and the four drugs were similarly priced. Classified as a **GREEN** drug in line with the other NOACs. It was agreed that the Guideline Group would look at the place of edoxaban in the atrial fibrillation guideline. TA 356 Ruxolitinib for treating polycythaemia vera (terminated appraisal). Classified as a **BLACK** drug.	**SD** **SD**
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Dulaglutide – BROWN 2nd line to exenatide MR Evolucumab - BLACK Abasaglar (insulin glargine biosimilar) - GREEN 1st line insulin glargine preparation in all new patients Lantus (insulin glargine) - GREEN 2nd line long-acting analogue insulin Nivolumab – RED (NHS England commissioned drug) Pembrolizumab - RED (NHS England commissioned drug) Ciclosporin eye drops – RED Toujeo - BLACK Edoxaban - GREEN Ruxolitinib -BLACK (terminated appraisal)	

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16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Aripiprazole and pregabalin – To be taken off. Glaucoma guidance – To be brought to the November meeting. Free of charge schemes – To be brought to the November meeting. Winterbourne review – To be taken off. Oral thrush – To be taken off. Midodrine (Bramox) – To be brought to the December meeting.	 **SD** **ST** **SD** **SD** **SD** **SD**
17.	**GUIDELINE GROUP**	
	The summary of key messages arising from the meeting held in September 2015 was noted. Mr Dhadli highlighted the following: • Oral anticoagulation guidance – This would be amended to warfarin monitoring guidance. It was noted that comments were awaited from DTHFT and the guidance would be discussed at the November JAPC meeting. • Non-malignant chronic pain in primary care – This would be discussed at the November JAPC meeting. • Chlamydia guideline – National guidance was awaited. • Derbyshire falls guideline – To be discussed at the November meeting. • Management of OAB – To be discussed at the November meeting.	 **SD** **SD** **SD** **SD**
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Burton Hospitals Drugs and Therapeutic Committee 14/09/15 • CRHFT Drugs and Therapeutic Committee 15/09/15 • Clinical Commissioning Policy Advisory Group 13/08/15 • DTHFT Drugs and therapeutic Committee 18/08/15 • Nottinghamshire Area Prescribing Committee 17/09/15	
19.	**ANY OTHER BUSINESS**	
	(a) Mr Dhadli stated that the Guideline Group had considered a statement from the Clinical Effectiveness Unit about the Faculty of Sexual and Reproductive (FSRH) response to new data on quick-starting hormonal contraception after use of ulipristal acetate 30mg (ellaOne) for emergency contraception. A summary of the statement from the FSRH would be included in the formulary chapter and added to the October bulletin with a message to request that prescribing leads and Practice Managers cascade as appropriate. (b) Mr Newman reported that the DTHFT pharmacy department would be hosting a placement for a Care Quality Commission (CQC) Medicines Inspector for one month in November 2015. It was agreed that this officer would be able to attend a JAPC meeting as part of a programme of attendance at meetings which concerned the governance of medicines.	**SD**
20.	**DATE OF NEXT MEETING**	
	Tuesday, 10th November 2015 at 1.30pm in the Post Mill Centre, South Normanton.	