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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 12th April 2016

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Evolocumab	RED (re-classified from BLACK)
Alirocumab	RED (re-classified from BLACK)
Lurasidone	BLACK (re-classified from RED)
Brivaracetam	RED
Etanercept (Benepali®) Biosimilar	RED
Ruxolitinib	RED (re-classified from BLACK) as NICETA386
Nitisinone (Orfadin)	RED

Clinical Guidelines
Managing Behaviour Problems in Patients with Dementia (BPSD) Policy

Patient Group Directions
Measles, Mumps and Rubella (MMR) Vaccine.
Pneumococcal Polysaccharide Vaccine (PPV)

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
North Derbyshire CCG	
Dr C Emslie	GP
Dr T Narula	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Dr R Dewis	Consultant in Public Health Medicine
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 Foundation Trust	
Mr M Steward	Head of Medicines Management
In Attendance:	
Dr N Jones	GP ST3
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Ms J Town and Dr M Watkins. Dr Narula was welcomed to JAPC as a GP representative from North Derbyshire CCG.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Neonatal Hepatitis B immunisation	
4.	**MINUTES OF JAPC MEETING HELD ON 8 MARCH 2016**	
	The minutes of the meeting held on 8th March 2016 were agreed as a correct record after the following amendments: Ulipristal - Amend to: Action: 'Mr Shepherd would ascertain the position of the CRHFT gynaecologists.' Medical Devices – Amend to: 'Mr Dhadli highlighted that the following were the only changes in the East of England document.' PCSK9 Inhibitors – Amend to: 'NICE TAs for both evolocumab and alirocumab were due to be published in April 2016 and June 2016 respectively' and amend to: Agreed: 'Evolocumab and alirocumab would be left as BLACK drugs pending NICE TAs.' Cellulitis - 'One of the main changes made concerned the flowchart on page 12 when for a patient body weight under 70kg the antibiotic teicoplanin dose had been changed to initially 800mg I.V stat then 400mg once daily starting 24 hours later.' Dymista – Amend to: 'Agreed: Beclomethasone nasal spray (as beconase) classified as **GREEN** 1st line. Mometasone 50mcg nasal spray classified as **GREEN** 2nd line drug. Dymista is **BROWN** after Specialist Initiation. All other nasal sprays are **GREEN** 3rd line in order of cost.'	
5.	**MATTERS ARISING**	
a.	**<u>Management of Sub-Therapeutic INR in Medical Patients</u>** Dr Mott reported that Ms Braithwaite, from CRHFT, and Dr McKernan, from DTHFT, had both been attempting to reach consensus about the management of those patients who had a sub-therapeutic International Normalised Ratio (INR) and the use of low molecular weight heparins (LMWH) for this but nothing further had been heard. JAPC was reminded that a key issue was the need to provide guidance for those providers in general practice and the community pharmacists who delivered the anticoagulation service to patients in the community. The two areas where guidance would be useful were for: • Patients following shared care arrangements of LMWH who do not achieve therapeutic INR • Patients on long term warfarin whose INR falls below the therapeutic level In addition, Dr McKernan had referred to guidelines from the British Committee for Standards in Haematology (BCSH) on oral anticoagulation with warfarin which indicated that sub therapeutic INR was only critical for the group of patients in the first month after acute VTE.	

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	Agreed: The Guideline Group would be requested to consider the points made by Dr McKernan and comments to be supplied by Ms Braithwaite and try and reach a consensus on the use of LMWH in this group of patients. This would then be brought back to JAPC for ratification.	**SD**
b.	**<u>Ulipristal</u>** It had been agreed that a single shared care pathway for symptomatic fibroids in pre-menopausal women and the place of Ulipristal Acetate in this would be developed by the Guideline Group. JAPC noted that the dates for Guideline Group meetings had now been changed so some of the actions agreed at the last meeting may not yet have been undertaken.	**SD**
c.	**<u>Midodrine Primary Care Prescribing Guideline</u>** Further comments from the specialists had been received after papers had been circulated to JAPC members. The guidance in light of the comments would be discussed by the Guideline Group and brought back to JAPC for further consideration.	**SD**
d.	**<u>Methotrexate Shared Care</u>** This would be brought to the May JAPC meeting.	**SD**
e.	**<u>Patient/Public Involvement in JAPC</u>** Dr Mott reported that he had contacted Healthwatch Derbyshire to ascertain whether a representative from the organisation could undertake the responsibilities involved in the patient/public role on JAPC but had been informed that there was nobody available who could contribute to the discussions at the meetings in a meaningful way. Dr Mott highlighted that this was still a significant gap as decisions made by JAPC needed to be publicly accountable but the identification of a suitable representative remained challenging.	
f.	**<u>PCSK9 Inhibitors</u>** Mr Dhadli advised JAPC that the DTHFT and CRHFT cardiologists and lipidologists had been asked for their views on the place in therapy of the first two PCSK9 inhibitors, evolocumab and alirocumab, which were a new class of drugs that had been shown to lower LDL cholesterol levels. NICE TAs for both evolocumab and alirocumab were due to be published in April 2016 and June 2016 respectively and both were currently classified as BLACK drugs. The cardiologists and lipidologists had indicated that it would be advisable to wait to see if the NICE TAs were positive and, if so, should then be taken for discussion at the DTHFT and CRHFT Drugs and Therapeutic Committees (DTCs). It was highlighted that these drugs would be tariff excluded and a defined Derbyshire-wide pathway for their use was needed. During discussion Mr Dhadli stated that the numbers of patients who would be eligible for PCSK9 inhibitors was unknown and Mr Hulme highlighted the need to ascertain the degree of activity and how this would fit in the pathway. **Agreed:** Evolocumab and alirocumab re-classified as **RED** drugs pending the publication of the NICE TAs and the development of a Derbyshire-wide pathway by the DTHFT and CRHFT Drugs and Therapeutic Committees.	**WG/MS**

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	Agreed: The costs and activity associated with evolocumab and alirocumab, together with the defined pathway, would be discussed by JAPC at the July meeting.	**SD**
6.	**NEW DRUG ASSESSMENTS**	
a.	**Lurasidone** Dr Taylor reported that the DHcFT Drugs and Therapeutic Committee had discussed lurasidone for schizophrenia in adults in the light of both old and new evidence and recent drug company activity but had concluded that its use was not recommended and its current traffic light classification of RED, as assigned by JAPC in October 2014, should therefore be changed to BLACK. It had been noted that the current traffic light classification of RED could be misinterpreted to indicate that it could be prescribed. Mrs Needham referred to those patients from outside Derbyshire who were already on lurasidone and that a classification of BLACK for lurasidone would make its continued prescribing difficult. However it was highlighted that there was provision in the traffic light classification to allow patients who have started treatment with the drug prior to the black designation to be able to continue treatment until their clinician considered it appropriate to switch or stop at the next medication review. **Agreed:** Lurasidone classified as a **BLACK** drug for new patients.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**Managing Behaviour Problems in Patients with Dementia (BPSD)** Mr Dhadli reported that there were currently no major changes to the existing guideline which was due to expire at the end of April 2016. **Agreed:** JAPC ratified an extension to the Managing Behaviour Problems in Patients with Dementia (BPSD).	**SD**
b.	**Management of Chronic Heart Failure with Left Ventricular Systolic Dysfunction** The local Heart Failure guidance had expired in October 2014. Mr Dhadli advised that the Scottish Intercollegiate Guidelines Network (SIGN) had issued SIGN 147 'Management of Chronic Heart Failure' in March 2016 which provided evidence-based recommendations and best practice guidance on the management of patients with chronic heart failure. This SIGN guidance had been used as a reference to update the local guidance on the management of chronic heart failure which had been circulated to the cardiologists at CRHFT and DTHFT, and also to the DCHSFT specialist heart failure nurses. Mr Dhadli highlighted that a significant number of changes had been made to this draft guidance and that some consultees had already conveyed comments. JAPC was requested to make comments on the draft guidance which was due to be discussed by the Guideline Group at the end of April. Mr Dhadli highlighted that the monitoring of spironolactone needed local agreement as this varied depending on the reference source used (e.g. BNF, CKS, SIGN) **Action:** Comments on the draft guidance to be conveyed to Mr Dhadli by 22 April 2016.	**All**

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c.	**Diabetes Type 2 Guidance in Adults** Mrs Qureshi reported that a draft of the new type 2 diabetes in adults guidance had been developed based on the recommendation contained in NICE NG 28 'Care and management of type 2 diabetes in adults (aged 18 and over)'. It was highlighted that this was the first draft and would be further updated in the light of comments received from JAPC members and the other consultees from the acute trusts. In connection with the reference to diabetes education in the guidance Dr Narula highlighted that the Diabetes and You programme was only used in North Derbyshire and Hardwick CCGs whereas the X-PERT health diabetes programme would be used in Southern and Erewash CCGs. It was agreed that the guideline should refer to a 'structured education programme' in the generic form. Dr Narula also advised that the reference to metformin + GLP1 agonist in dual therapy was incorrect as GLP1 only applied to triple therapy. Mrs Qureshi would check this in the NICE guidance. Dr Mott queried why repaglinide, which was considered to be both clinically effective and cost effective in adults, was not referred to in other sections of the guidance and its place in therapy would need to be determined. JAPC was requested to make comments on the draft guidance which was due to be discussed by the Guideline Group at the end of April. The draft guidance would also now be sent to consultant diabetologists for comments. **Action:** Comments on the draft guidance to be conveyed to Mrs Qureshi by 22nd April 2016.	**SQ** **SQ** **SQ** **All**
8.	**PATIENT GROUP DIRECTIONS**	
a.	**Administration of Measles, Mumps and Rubella (MMR) Vaccine** The Public Health England/NHS England Patient Group Direction for measles, mumps and rubella (MMR) vaccine was noted by JAPC. **Agreed:** JAPC agreed the PGD for the administration of Measles, Mumps and Rubella (MMR) Vaccine would be added to the Medicines Management website.	**SD**
b.	**Pneumococcal Polysaccharide Vaccine (PPV)** The Public Health England/NHS England Patient Group Direction for Pneumococcal Polysaccharide Vaccine (PSV) was noted by JAPC. **Agreed:** JAPC agreed the PGD for the administration of Pneumococcal Polysaccharide Vaccine (PPV) would be added to the Medicines Management website.	**SD**
9.	**SHARED CARE**	
a.	**Acetylcholinesterase Inhibitors and Memantine** Dr Taylor reported that the decision made by JAPC in December 2015 to revoke the requirement for a shared care agreement for rivastigmine for behavioural problems and psychosis in patients with Parkinson's disease dementia (PDD) complex as no biochemical monitoring was required. This had prompted a discussion at DHcFT Drugs and Therapeutic Committee when it had been noted that a similar approach might be taken for the indication of dementia and that the current traffic light criteria for amber classification indicated that AChE did not warrant a shared care classification.	

Item		Action
	It had been agreed therefore that a request be made to JAPC in view of this and, in order to ensure parity of care for people with dementia, for similar reclassifications to be made for other dementia medicines. During discussion Dr Mott commented that the main reason for the apparent discrepancy was the volume and scale of work in primary care which would result if all the dementia drugs were re-classified as GREEN. There would be significant concern from primary care about the potential for an increased workload without any additional funding. Dr Mott highlighted that the traffic light position of these drugs was the end not the start of the commissioning process and that he had been involved in the development of a paper in conjunction with Hardwick CCG as the lead commissioner of mental health services in Derbyshire. This paper would explore the options for the management of these patients and ensure that DHcFT was not overwhelmed with patients while at the same time ensuring that primary care was supported to manage the additional workload. Dr Mott added that it would not be desirable to change the traffic light classification until the service and care for the patients concerned had been properly commissioned – this was currently not the position. Dr Emslie stated that there would be concern if primary care was expected to care for the patients who were discharged from the service without additional funding and there must be adequate follow up. The current shared care was primarily concerned with monitoring and it would be desirable to commission a new pathway which would advise GPs on such aspects as when to discontinue or swap a drug before any decision was made to change the traffic light classifications of the drugs. **Agreed:** The traffic light classifications of the acetylcholinesterase Inhibitors and memantine to remain unchanged as **AMBER.** Dr Mott would continue to keep this issue high on the agenda within the CCGs.	**SD** **AM**
10.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations: New drug launches in the UK: Brivaracetam (Briviact) – Classified as **RED.** Etanercept biosimilar – SB4 (Benepali) – Classified as **RED** – Cost effective etanercept. Guanfacine (Intuniv) - For attention-deficit hyperactivity disorder (ADHD) in patients aged six to seventeen years - Leave unclassified and await request from community paediatricians. JAPC noted that the current ADHD shared care was currently being updated. Panobinostat (Farydak) – NHS England. Classified as **RED.** New formulation launches in the UK: Nitisinone (Orfadin) – NHS England. Classified as **RED.**	**SD** **SD** **SD** **SD**

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11.	**MISCELLANEOUS**	
a.	**Conflict of Interest** Members were requested to complete the JAPC declaration of interest form as required in the terms of reference and return to Mr Dhadli.	**All**
b.	**Controlled Drugs** JAPC noted that NHS England North Midlands had issued a new online reporting tool and that all primary care contractors had been encouraged to register to use this.	
c.	**Etanercept and Infliximab Biosimilar** Mr Dhadli referred to the data which had been presented at the Congress of the European Crohn's and Colitis Organisation (ECCO) which supported the switching of patients from reference infliximab to the cheaper biosimilar infliximab. This was relatively straight forward in the patients who had the drug administered at the hospital but Dr Goddard highlighted a possible safety issue associated with the swapping of those patients who had infliximab (as Remicade®) at home, although it was considered that the risk would be very low. This may necessitate bringing back those patients who had infliximab at home to hospital in order to have a test dose of the biosimilar. Mr Newman advised that the swapping of gastro-enterology patients to infliximab as Remsima was due to be discussed by the DTHFT Drugs and Therapeutic Committee and Finance Sub-Committee. Mr Dhadli advised that UK marketing authorisation had now been granted to Benapali® which was an etanercept biosimilar to the originator Enbrel but there were some differences to note between the two products: • Benepali® was only licensed for adults aged 18 and over while Enbrel® is licensed in children from the age of two years. The majority of use is commissioned by CCGs and for use in adults. The use of a biosimilar therefore represented a significant QIPP opportunity for the local health economy. • Benepali® was currently only available as a 50mg pre-filled pen or syringe as opposed to Enbrel® which also has a 25mg dose. Mr Dhadli stated that only small proportion of patients will be using the 25mg twice weekly form. • The Benepali® pre-filled pen was an auto-injector device compared to the Enbrel® pen which required the patient to press a button to administer the dose. Benepali device may be preferred by patients because of its ease of use, considering the primary disease in question (arthritis). • The rubber needle sheath for the Enbrel® pen and syringe contained latex while Benepali® was latex-free. • Etanercept was used across a variety of care settings. Mr Newman stated that the switch to Benapali® was due to be discussed by the DTHFT Drugs and Therapeutic Committee and Finance Sub-Committee. Mr Shepherd advised that new patients had been started at CRHFT on Benepali® at the beginning of April 2016 and existing patients would be switched from June.	

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d.	**Medicines Optimisation Key Therapeutic Topics** Mr Dhadli reported that the 2016 update of 'medicines optimisation: key therapeutic topics' had now been published and, following consultation and feedback from NHS and partner organisations, two topics had now been retired – laxatives and minocycline. Three topics had also been added - biosimilar medicines, non-vitamin K antagonist oral anticoagulants (NOACs) and acute kidney injury (AKI): use of medicines in people with or at increased risk of AKI. The Medicines Optimisation Key Therapeutic Topics were noted by JAPC.	
e.	**Primary Care Rebates** Mrs Qureshi advised JAPC that primary care rebates for carbocisteine sachets had been agreed and rebates for fentanyl patches (Fencino®) and goserelin (Zoladex®) had been agreed for continuation across Derbyshire.	
12.	**JAPC BULLETIN**	
	Mr Newman queried why a reference to the two new lipid-regulating drugs had been included in the JAPC bulletin. It was agreed that this section should be removed from the bulletin. The revised bulletin was ratified by JAPC.	**SD** **SD**
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for March 2016 was noted. Mr Dhadli highlighted the following MHRA advice: • Trametinib (Mekinist▼): risk of gastrointestinal perforation and colitis.	
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in March 2016: TA 23 Update: Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer) – Temozolomide already classified as a RED drug. TA386 Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis - This guidance replaced TA 289 issued in 2013 in which ruxolitinib had not been recommended within its marketing authorisation for the treatment of disease-related splenomegaly or symptoms in adults with myelofibrosis and had been assigned a BLACK traffic light classification. Ruxolitinib was now recommended and was a NHS England drug. Ruxolitinib re-classified as a **RED** drug.	**SD**
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Evolocumab – **RED** (re-classified from BLACK) Alirocumab – **RED** (re-classified from BLACK) Lurasidone – **BLACK** (re-classified from RED) Brivaracetam – **RED**	

Item		Action
	Etanercept (Benepali®) Biosimilar – **RED** Ruxolitinib – **RED** (re-classified from BLACK)	
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Immunomodulating drugs - Subcutananeous methotrexate update to be brought to the May 2016 JAPC meeting. LMWH bridging guidance – To be brought to the May 2016 JAPC meeting. Ulipristal for uterine fibroids – To be brought to the May 2016 JAPC meeting. Type 2 Diabetes Guidance for Adults – To be brought to the June 2016 meeting. Heart Failure Guidance – To be brought to the May 2016 JAPC meeting.	**SD** **SD** **SD** **SD**
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• CRHFT Drugs and Therapeutic Committee 15/03/16 • DTHFT Drugs and Therapeutic Committee 16/02/16 • DHcFT Drugs and Therapeutic Committee 28/01/16 • Sheffield Area Prescribing Group 21/01/16 • Sheffield Area Prescribing Group 19/11/16 Mr Dhadli highlighted the following items from the minutes: CRHFT Drugs and Therapeutic Committee - The latest data summarising the impact of the decision to reduce the use of oral oxycodone products. It had also been noted that the Trust was in the top ten hospitals in the country for the uptake of bio-similar infliximab. This was noted by JAPC recognising significant savings to the NHS. DHcFT Drugs and Therapeutic Committee – Shared care for attention deficit hyperactivity disorder (ADHD) to be reviewed and updated. Sheffield Area Prescribing Group – Guidance on the off-label use of bisphosphonates for metatastic breast cancer may be coming from the Cancer Network or possibly nationally. It was highlighted that JAPC should be mindful of any developments and would need to endorse the off-licence prescribing of this locally.	
17.	**ANY OTHER BUSINESS**	
a.	**Hepatitis B** Dr Mott referred to discussions about the hepatitis B immunisation schedule for babies born to hepatitis B positive or high risk mothers. A new clinical pathway for hepatitis B had recently been introduced which included the immunisation schedule, communication and role between healthcare professions and the twelve month test of immunity for the babies. With the latter it had been proposed that one option for this was to undertake a heel prick on the baby, although this could only be done by staff that had been appropriately trained, and the other option was to send the babies for serology for surface antigen antibodies (HBsAg).	

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	It was noted that the NHS England North Midlands Screening and Immunisation Area Team for Derbyshire and Nottinghamshire would be circulating more detailed information to general practices. Mr Dhadli referred to information which was already available concerning the responsibilities of primary care for such aspects as recording of vaccinations and advice as to the action to be undertaken if the results were positive. This would be included in the newsletter. Dr Mott added that it had been suggested that ante-natal care should indicate to primary care those babies which required the vaccinations and the heel prick or blood test.	**SD**
18.	**DATE OF NEXT MEETING**	
	Tuesday, 10th May 2016 at 1.30pm in the Post Mill Centre, South Normanton.	