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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 14 April 2015

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Escitalopram	**BROWN** (re-classified from BLACK)
Exenatide once weekly prefilled pen	**GREEN** as per local guidelines
Lamotrigine	**GREEN** after consultant/specialist initiation (includes extended non epilepsy indications)
Empagliflozin	**BROWN** consultant initiation (as per TA 336)
Pomalidomide	**BLACK** (as per TA 338)

Shared Care Guidelines

Colistimethate (Colomycin) for pseudomonal lung infection in ADULTS with bronchiectasis
Dementia shared care agreements to be extended to the end of March 2016 pending a review of the dementia services for Derby City and Derbyshire County.
Memantine, donepezil, rivastigmine & galantamine.

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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 D Fitzsimons	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Ms H Murch	Lead Pharmacist
Derby City Council	
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair - Drugs and Therapeutic Committee
Derbyshire Healthcare NHS Foundation Trust	
Ms S Bassi	Chief Pharmacist
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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1.	**APOLOGIES**	
	Dr R Dewis, Dr M Henn, Mr C Newman, Ms J Town and Dr M Watkins.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	No declarations of any other business were made.	
4.	**MINUTES OF JAPC MEETING HELD ON 10 MARCH 2015**	
	The minutes of the meeting held on 10th March 2015 were agreed as a correct record after the following amendments: Olodaterol: Amend to 'The SMC had originally rejected olodaterol based on a lack of sufficiently robust clinical evidence and economic grounds with economic comparisons made indirectly with indacaterol the other once daily LABA. A re-submission though was successfully made in December 2014 and accepted on cost minimisation grounds versus an indirect comparison against salmeterol.' Mr Dhadli referred to post meeting information from DTB (April 2015) which stated "…at present, we consider that there is insufficient evidence to recommend olodaterol over existing LABAs."	
5.	**MATTERS ARISING**	
a.	**Cancer Drugs Fund** Mr Hulme reported that the support expressed by JAPC for option 1 (chemotherapy to remain nationally commissioned by NHS England) in the NHSE paper had been formally conveyed via PAG.	
b.	**Bimatoprost – Discontinuation of 0.3% MDV** Dr Mott commented that CRH had never routinely used the 0.3% preparation of bimatoprost. Mrs Needham stated that there were some historic patients on 0.3% bimatoprost which the consultant ophthalmologists had agreed could be changed over to the 0.1% preparation. These patients would have their intraocular pressure measured at their next routine appointment unless any deterioration had been observed. For DHFT Dr Goddard advised that a letter had been sent to all GP practices about a switch from bimatoprost 0.3% to generic latanoprost. Mr Dhadli would amend the current bulletin to indicate what is happening in each hospital and for each practice to contact their medicines management team with any specific questions.	**SD**
c.	**Derbyshire Primary Care Rebates** Mr Dhadli reported that the paper had been developed to indicate that any pharmaceutical companies wishing to enter into a rebate scheme with any one of the Derbyshire CCGs would need to complete the PrescQIPP documentation. PrescQIPP would review the offer and assist the CCGs in managing the legal implications of entering into presented schemes. In the event of a positive recommendation by PrescQIPP this would be	

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	followed by a further Derbyshire review for a decision to be made locally via the Senior Prescribing Advisers Team (SPAT) and the Chief Finance Officer Panel (CF). Mr Dhadli added that SPAT and PrescQIPP had a framework by which they assessed rebates which included for example continuity of supply. Mr Dhadli assured the committee that Derbyshire has a clear and transparent process for the management of rebates. Mr Dhadli recommended that the SPAT principles should be added on the website as an appendix to the rebate form.	**SD**
d.	**Escitalopram** Ms Bassi reported that the definition of exceptionality and proposed change from BLACK to BROWN due to price reduction had been discussed by the DHcFT Drugs and Therapeutic Committee. The following exceptionality criteria had been agree by the DTC: 1. For patients already prescribed escitalopram and who had responded to treatment. 2. Patients who had previously experienced a good response from escitalopram and now required an anti-depressant. 3. On the recommendation from a tertiary centre on receipt of a consultant referral. Dr Mott queried why a recommendation from a tertiary centre had been proposed instead of secondary. Ms Bassi replied that this would enable all options to be covered and there had been cases where out of area consultants had recommended escitalopram but when patients had returned to DHcFT the use of this drug had not been supported. Mr Hulme queried why the use of other selective serotonin re-uptake inhibitors (SSRIs) had not been referred to in second criteria. Ms Bassi stated that escitalopram was not routinely used in DHcFT. It was agreed that the second criteria should be amended to include after formulary choices and should also be merged with the third so that the exceptions now had two criteria: 1. For patients already prescribed escitalopram and who have responded to treatment. 2. For patients who have had a good response to escitalopram for a previous episode after trying formulary choices or now require anti-depressant following recommendations from a tertiary centre. **Agreed:** Escitalopram re-classified from BLACK to a **BROWN** drug.	**SD**
e.	**Clozapine** Ms Bassi reported that DHcFT had completed the list by the end of March as previously agreed and a process for conveying appropriate information to the CCGs was underway. This work around clozapine would now be taken out of the JAPC action tracker.	**SD**
6.	**NEW DRUG ASSESSMENTS**	
a.	**New Exenatide Weekly Formulation** Mr Dhadli stated that in March 2012 JAPC had classified exenatide once weekly formulation in the light of NICE TA 248 as BROWN with exceptionality defined in a cohort of patients that required daily home visits from a nursing team.	

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	It had been noted at the time that the injected suspension had to be reconstituted immediately before administration using a non-touch technique, and this could prove to be difficult for patients with impaired dexterity or vision. Since then a new formulation of exenatide in a pre-filled pen had been identified in the March 2015 JAPC horizon scan which was easier to use. There was now a need therefore to determine whether the original traffic light classification should be changed as this had only allowed exceptional use in people who were able to manipulate the device. It was noted that this pre-filled pen would continue to be used in line with local diabetes guidance/ NICE TA 248 and that lixisenatide was still the preferred GLP1 agonist. The pen still requires several preparatory steps before a dose can be administered but less complex than its other form. **Agreed:** Exenatide Once Weekly pre-filled pen classified as a **GREEN** drug in line with local guidance.	
b.	**<u>Tiotropium for Asthma</u>** Mr Dhadli reported that JAPC had undertaken a review of this licence extension in December 2014 using the NICE medicines evidence commentary and a further NICE review March 2015 had recently been published. The review indicated that there were no differences between add-on therapy with tiotropium and placebo in patient-assessed asthma control and quality of life were small. Mr Dhadli highlighted the following: • Evidence at STEP 4 was largely based on extrapolation from trials of add-on therapy to ICS alone • It was unknown how the efficacy of tiotropium as add-on therapy compares with other active treatments recommended at step 4 of the British guideline on the management of asthma • Tiotropium was the only licensed for use in asthma when delivered using the solution for Respimat. Dr Mott commented that Tiotropium for asthma had previously been classified as a BROWN drug with specialist/consultant assessment and initiation. The hospital respiratory consultants would select patients appropriately for the use of tiotropium in asthma so the traffic light classification should be unchanged. Mr Dhadli also updated JAPC informing them that interest in prescribing tiotropium for asthma could grow and cited recent two large studies in but in moderate asthma. This would be use outside of licence (outside step 4 of SIGN/BTS). The trials also used ICS without a LABA. **Agreed:** The classification of tiotropium for asthma as a **BROWN** drug with specialist/consultant assessment and initiation to remain unchanged	
c.	**<u>Lamotrigine</u>** Ms Bassi reported that lamotrigine was currently classified as GREEN after consultant/specialist initiation for the indication of epilepsy only. A request had now been made for a traffic light classification to be assigned for the use of lamotrigine in bipolar disorder. JAPC were informed that lamotrigine was a recommended treatment option in NICE CG 185 “Bipolar disorder: the	

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	assessment and management of bipolar disorder in adults, children and young people in primary and secondary care" published in September 2014. Lamotrigine was often used in clinical practice but did not have a UK marketing authorisation for the treatment of bipolar disorder but was licensed to treat depressive episodes in people who have bipolar disorder. **Agreed:** Lamotrigine classified as **GREEN** after consultant/specialist initiation for the prevention of depression in people with bipolar disorder.	
7.	**CLINICAL GUIDELINES**	
a.	**NSTEMI RDH** Dr Goddard advised JAPC that prasugrel 10mg was now available in DHFT as an option in the guidelines for anti-platelet therapy in non-ST elevation ACS to be used alongside the ACS/NSTEMI pathway. This was in line with NICE TA 317. Mr Dhadli added that the patent expiry for prasugrel was listed as the end of 2017. **Action:** Mr Dhadli informed CRH that their ACS dual antiplatelet policy for NSTEMI/unstable angina had long expired. Martin agreed to bring this back to the next meeting.	**MS**
8.	**PATIENT GROUP DIRECTIONS**	
a.	**PGD Update** Mr Dhadli advised that there were two groups of Patient Group Directions (PGDs): those owned by NHS England covering the national screening and vaccination and immunisation programmes and those now owned by the CCGs. Public Health England had now employed a pharmacist to update the national PGDs although the local PGDs would remain the responsibility of the CCGs to update. The local PGDs which had now expired were now Hepatitis A - Adult (Derbyshire use only), Hepatitis A - Child (Derbyshire use only), Hepatitis A and Typhoid (Derbyshire use only), Hepatitis B - Adult (Derbyshire use only), Hepatitis B - Child (Derbyshire use only) and Typhoid (Derbyshire use only). In addition Levenolle was due to expire in November 2015, vitamin k in June 2015. Mr Dhadli highlighted that it would be necessary to decide whether to extend the local PGDs which had already expired by three months or remove them. Mr Dhadli proposed contact PHE to confirm which PGDs from all those we have listed need to be updated by the CCGs. Following discussion it was agreed that the local PGDs would be extended by a period of six months and included on the JAPC action tracker with medicines management team to lead on preparing new/updated versions.	**SD**
9.	**SHARED CARE GUIDELINES**	
a.	**Colomycin** Mr Dhadli reported that the existing shared care guideline for the use of nebulised colomycin injection (Colistin) in pseudomonas aeruginosa lung infections in adults with bronchiectasis (non-Cystic Fibrosis) had been updated. The updated shared care guideline had now clarified the consultant responsibility for monthly sputum monitoring and referred to the GP responsibilities for prescribing and checking for any exacerbations.	

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	Mrs Needham suggested that the section in GP responsibilities to prescribe the colomycin injection for nebulisation and sodium chloride 0.9% for injection 5ml plastic ampoules once a stable dosing regime has been determined by secondary care should be highlighted in the document. This was agreed. **Agreed:** JAPC ratified the Colomycin shared care guidelines with the agreed amendment.	**SD**
b.	**Dementia** Ms Bassi advised JAPC that the acetylcholinesterase Inhibitors shared cares of donepezil, rivastigmine and galantamine were due to expire in June 2015 and memantine for Alzheimer's disease was due to expire in May 2015. Ms Bassi added that the current dementia service for patients under shared care was being reviewed between provider and commissioner and it was therefore requested that these shared care agreements be extended to December 2015 to allow time for this review to be concluded. Dr Mott referred to correspondence between him and Mr David Gardner, Mental Health commissioner, and Dr Mark Whittingham, DHcFT Consultant Psychiatrist/Associate Clinical Director, where he had confirmed the need to ensure that the proposed dementia service was properly commissioned and supported in general practice before any move away from shared care could be agreed by JAPC. **Agreed:** Both sets of shared care agreements to be extended to the end of March 2016 pending a review of the dementia services for Derby City and Derbyshire County.	**SD**
10.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions, drug discontinuations and new evidence reviews: New drug launches: Infliximab biosimilar (Remsima and Inflectra) – Already classified as RED. New drug formulations: Tacrolimus (Envarsus) – Oral already classified as RED. Licence extensions: Aflibercept (Eylea) Bortezomib (Velcade) Collagenase clostridium histolyticum (Xiapex) Insulin degludec (Tresiba) Lenalidomide (Revlimid) Mr Dhadli added a new section to the horizon scan summary. This table included expected NICE new evidence reviews with a proposed action: Aclidinium/ formoterol for COPD, April 2015 - For consideration by the guideline group in June (COPD)	

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	Brinzolamide/brimonidine for glaucoma, March 2015 - No decision and await clinician request from the provider Drugs and Therapeutic Committee. Budesonide for Induction of remission in patients with mild to moderate active ulcerative colitis, June 2015 - To be considered by JAPC in July. Degludec/ liraglutide for type 2 diabetes, June 2015 - No action and await NICE guideline. Dulaglutide for type 2 diabetes, June 2015 - To be considered by JAPC in July 2015. Nab-paclitaxel for non-small cell lung cancer, June 2015 - No action.	
11.	**MISCELLANEOUS**	
a.	**NICE Frequently asked Questions on TAs** Mr Dhadli advised that NICE had issued guidance on achieving and demonstrating compliance with the NICE Technology Appraisal (TA) and Health Service Technology (HST) guidance. Mr Dhadli highlighted the following: • Statutory responsibility to make funding available within three months of publication with the only exception if the technology was not relevant to the care provided by the organisation. • All NICE approved treatments must be included in local formularies for use in line with the TA or HST recommendations and with no additional restrictions. • Providers and commissioners must not restrict access to NICE-approved medicines by adding to or modifying the clinical eligibility criteria stated in the TA or HST.	
b.	**New Oral Anticoagulants – East Midlands Strategic Clinical Network (EMSCN) Guideline** Mr Dhadli reported that the EMSCN had developed an anticoagulation algorithm guideline some time ago as an aid to clinicians to decide upon the most appropriate anticoagulation option for a patient once a decision to anticoagulate has been made. This algorithm was being shared with CCGs and medicines management groups in the East Midlands as an aid to support the updating of local prescribing guidelines following publication of the NICE Guidelines for Atrial Fibrillation in June 2014. Because there were key differences between the local AF guideline and the EMSCN algorithm and template, the North Derbyshire and Hardwick Prescribing Sub Group had agreed to develop a local algorithm and template for use by practices. During discussion Dr Parkin stated that the local algorithm had the potential to be of value to GPs when advising patients about choice of warfarin or New Oral Anticoagulant (NOAC). Mr Dhadli informed JAPC that he was aware of the EMSCN algorithm when the local AF guidance was written and had indeed debated on whether to include something similar. He advised JAPC that the logistical arm of the flow chart was useful but questioned the clinical criteria. With the exception of SPC and licensing restrictions Mr Dhadli stated that no head to head studies suggested one NOAC in preference over another and to do so was misleading. A clear statement is included in the algorithm to make it clear that no head to head studies have taken place and all anticoagulants in the algorithm are recommended as options by NICE and commissioners may only recommend an individual drug after a patient and	

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	prescriber have discussed all the treatment options and only if they have no preference about which medicine they wanted to use. Mr Hulme commented that the algorithm was more of an implementation tool rather than formal guidance and assisted clinicians in making decisions about the appropriate product to use. Dr Emslie referred to the use of rivaroxaban in a compliance aid and it was agreed that this should be included. Mrs Needham advised that it would be an appendix to the template which already had a link to the Derbyshire AF guideline so the emphasis was on implementation. Dr Parkin highlighted that this was East Midlands guidance adapted for local use by the medicines management team which would be developed into a template for use on the various primary care clinical systems. Dr Mott commented that the appropriate place for the algorithm would be on the website and as an appendix to the AF guidance.. **Agreed:** JAPC ratified the local algorithm for inclusion in the Derbyshire AF guidance.	**SD**
c.	**Australian Statement on Homeopathy** JAPC noted the Australian Government's National Health and Medical Research Council assessment of homeopathy which had concluded that, based on the assessment of the evidence of effectiveness of homeopathy, there were no health conditions for which there was reliable evidence that homeopathy was more effective than placebo.	
d.	**Prescribing Specification** Ms Bassi reported that feedback had been received from DHcFT consultants that point 15 of the prescribing specification should be amended to include 'off-label' usage and practice. This was agreed by JAPC.	**SD**
12.	**JAPC BULLETIN**	
	Mr Dhadli highlighted the inclusion of a statement that the manufacturer of Lumigan (bimatoprost) was discontinuing the 300mcg 3ml product with effect from 30th April 2015. The March 2015 JAPC bulletin was ratified.	**SD**
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Update for March 2015 was noted.	
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 2015. NICE TA 335 Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome - A new strength of rivaroxaban (2.5mg) had been launched in the UK in October 2014. The licensed indication for rivaroxaban 2.5mg twice daily is used in combination with aspirin alone or with aspirin plus clopidogrel or ticlopidine for the prevention of atherothrombotic events in adult patients after an ACS with elevated cardiac	

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	biomarkers. The costing template assumes that all admissions with STEMI and NSTEMI who were eligible for treatment went on to have one of the available treatments. The current treatment options include aspirin + ticagrelor, aspirin + prasugrel, and aspirin + clopidrogrel. It had been assumed that approximately 99% of admissions with STEMI and NSTEMI eligible for secondary prevention of atherothrombotic events currently receive aspirin + clopidogrel although there was wide variance in practice. The NICE template assumed only patients currently treated with aspirin ± clopidrogrel would include the addition of rivaroxaban (aspirin + clopidogrel + rivaroxaban). This would be an addition cost to existing therapy. The manufacturer anticipated that the market share of rivaroxaban would increase from 0% - 5% in year 1 (2015) and rise to 14% by year 3 (2017). During discussion Mr Dhadli advised JAPC about the trials and economic analysis behind the publication of the NICE TA and highlighted some concerns about the conclusions which had been reached including duration beyond twelve months and whether rivaroxaban would be used with aspirin without clopidogrel. It was agreed that the cardiologists from RDH and CRH be requested for their views on the uptake of rivaroxaban, whether they intended to use it widely or in subgroups of the population with ACS before a traffic light classification was assigned and discussed again at the May JAPC meeting. NICE TA 336 Empagliflozin in combination therapy for treating type 2 diabetes - This provided an additional treatment option for people with type 2 diabetes alongside other treatment options which have similar costs and outcomes. It was estimated that approximately 1950 people per 100,000 would be potentially eligible for treatment with empagliflozin. There were several comparator drugs available and the number of patients who go on to actually have empagliflozin would be a subset of this group. It was highlighted that empagliflozin, together with the other TAs for dapagliflozin and canagliflozin, had a licence for dual therapy, triple therapy (exception dapagliflozin as part of clinical trial only) and with insulin. Dapaglifozin and canagliflozin had both been assigned a traffic light classification of BROWN after consultant/specialist initiation. Classified as BROWN on consultant/specialist initiation. Empagliflozin would be added to the diabetes guidelines with dapagliflozin and canagliflozin highlighting cost and licencing differences. TA 337 Rifaximin for preventing episodes of overt hepatic encephalopathy – The cost of implementing the guidance was estimated over three years as follows: Southern Derbyshire CCG - £28,675 - £78,908 North Derbyshire CCG - £15,672 - £43,126 Erewash CCG - £5,342 - £14,700 Hardwick CCG - £6,206 - £17,077 Already classified as GREEN for hepatic encephalopathy following specialist initiation with a current 12 month spend of £42k across all of Derbyshire. Mr Dhadli updated JAPC with a summary of the TA.	

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	Questions still remain over the long term efficacy of rifaximin to treat hepatic encephalopathy noting also that ICER was close to the top end of the range normally considered cost effective by NICE. TA 338 Pomalidomide for relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib – Classified as BLACK. CG 28 Depression in children and young people: Identification and management in primary, community and secondary care – Consideration could be given for combined therapy (fluoxetine and psychological therapy) for initial treatment of moderate to severe depression in young people as an alternative to psychological therapy followed by combined therapy. NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes – This would be discussed by the CCG prescribing groups.	
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Escitalopram - BROWN Exenatide weekly – GREEN as per local guidelines Lamotrigine – GREEN after consultant/specialist initiation (includes extended non epilepsy indications) Empagliflozin – BROWN consultant initiation (as per TA 336) Pomalidomide – BLACK (as per TA 338)	
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Hyperprolactinaemia – To be brought to the May JAPC meeting. Pathology reporting of non-HDL – To be taken off the list. Lithium monitoring - Lithium shared care to be updated.	**SD** **SD**
17.	**GUIDELINE GROUP**	
	The summary of key messages was noted. Mr Dhadli highlighted the following: • Temazepam classification changed from green to brown 2nd line to zopiclone for short term use only. • Diabetes type 2 Guideline updated with recent advice from SPC about renal function with liraglutide.	
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• DHcFT Drugs and Therapeutic Committee 26/02/2015 • DHFT Drugs and Therapeutic Committee 17/02/2015 • Chesterfield Drugs and Therapeutic Committee 17/03/2015	

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19.	**ANY OTHER BUSINESS**	
	Dr Mott reported that Mr Newman had queried whether JAPC should have its own logo which could be placed on all papers relating to the work of the committee. This would be similar to the logos used by other neighbouring Area Prescribing Committees. Following discussion members agreed that a logo for Derbyshire JAPC would not be advantageous.	
20.	**DATE OF NEXT MEETING**	
	Tuesday, 12th May 2015 at 1.30pm in the Post Mill Centre, South Normanton.	