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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 10 September 2013

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Insulin Degludec 200units/ml	BROWN Specialist Initiation **Restricted use**. Insulin resistant patients requiring >150 units/day who would otherwise be started on Humulin R U-500- Degludec 200 unit formulation.
Insulin Degludec 100units/ml	BROWN Specialist Initiation **Restricted use.** Treatment option in those being considered for insulin pumps – Degludec 100 unit formulation.
Trospium	GREEN 3rd line (as per local OAB guideline)
Darifenacin	GREEN 3rd line (as per local OAB guideline)
Fesoterodine	GREEN 3rd line (as per local OAB guideline)
Mirabegron	GREEN 3rd line (as per local OAB guideline)
Solifenacin	GREEN 3rd line (as per local OAB guideline)
Caffeine (citrate)	RED
Everolimus as per TA 295	BLACK

Clinical Guidelines

Asthma Guidelines (Adult)
Asthma Guidelines (Children)
Prevention of Stroke and Systemic Embolism in AF with Warfarin and NOACs
Neuropathic Pain
Non-malignant Chronic Pain Management in primary care-
Acne Pathway- NDCCG
Emollient Prescribing
Glucose Control in Type 2 Diabetes
Management of overactive bladder (OAB) in primary care

Patient Group Directions

Shingles (herpes zoster) Vaccine (Zostavax)

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Present:	
Derbyshire County Council	
Dr J Bell	Assistant Director of Public Health (Chair)
Mrs S Qureshi	NICE Audit Pharmacist
Southern Derbyshire CCG	
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Dr A Mott	GP
Dr I Tooley	GP
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	
Dr M Henn	GP
Derby Hospitals NHS Foundation Trust	
Dr F Game	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	
Ms C Duffin	Pharmacist
Derbyshire Community Health Services NHS Trust	
Mr M Steward	Chief Pharmacist
Lay Representative	
Dr C Shearer	Healthwatch Derbyshire
In attendance	
Mr A Thorpe	Derby City Council Public Health
Dr A Wilson	F2 Trainee

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Item		Action
1.	**APOLOGIES**	
	Mrs L Hunter.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	Dr Henn declared an interest in the provision of an anti-coagulation service by his practice to neighbouring practices within Erewash CCG. In connection with the asthma guidelines Dr Henn stated that he had attended a sponsored asthma education event.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	There were no declarations of any other business.	
4.	**MINUTES OF JAPC MEETING HELD ON 13 AUGUST 2013**	
	The minutes of the meeting held on 13 August 2013 were agreed as a correct record with the following amendments: Traffic Lights – Amend to: Eslicarbazepine Shared Care Guidelines – Amend to: Acetycholinesterase Inhibitors Guidelines Sub-Group Terms of Reference – Amend to: Dr Game stated that the RDH would not be able to commit a single named person to join the sub-group but would ensure that there was representation at each sub-group meeting at appropriate times relevant to the agenda. Dapagliflozin – Amend to: Dr Game commented that dapagliflozin needed to be added to the guideline which was being developed by the Guideline Group and would probably come after DPP4 inhibitors. Pentoxyfilline – Amend to: Pentoxyfilline for healing venous drug ulcers was not used in Derbyshire and therefore classified as a BLACK drug.	
5.	**MATTERS ARISING**	
a.	**<u>JAPC Terms of Reference</u>** Dr Bell requested that the CCG representatives confirm by email that the revised JAPC terms of reference had been ratified by their respective CCG Boards.	**CCG Leads**
6.	**NEW DRUG ASSESSMENT/TRAFFIC LIGHT ADDITION**	
a.	**<u>Degludec</u>** Dr Game stated that insulin degludec was a neutral, soluble, ultra-long-acting insulin analogue for the treatment of diabetes in adults as a basal insulin replacement. Degludec was available in two strengths and being proposed for two different patient groups: U100 for patients with documented nocturnal hypoglycaemia and U200 to replace U-500 insulin in insulin resistant patients. The submission for the use of degludec had come via the RDH Drugs and Therapeutic Committee which had accepted its use on the RDH formulary for only two conditions: • Patients who had significant problems with documented nocturnal hypoglycaemia that would otherwise have been started on insulin pump therapy which was expensive due to the costs of pumps and consumables. • Patients who currently required very high doses of insulin or be considered	

	for the concentrated Humulin R U-500 which was only available in vials and posed significant governance issues in terms of prescribing and dispensing. Mr Dhadli reported that there have been several comprehensive literature reviews of insulin degludec. A SMC review in March 2013 had not recommended its use. The FDA was awaiting some cardiovascular outcomes before giving approval in the United States. MTRAC had reviewed degludec in February 2013 and they had allocated a lower place and weaker evidence for the broad indication of diabetes in adults. No safety issues had been identified by the EMA about degludec but it was considerably more expensive than insulin analogues and may offer few or no meaningful advantages for the majority of users. There had been two reviews by NICE. The first in type 2 diabetic patients which had indicated non-inferiority to insulin glargine in terms of hypoglycaemic control and HbA1c. In an analysis of secondary endpoints insulin degludec reduced the rate of overall nocturnal hypoglycaemia compared with glargine. However the differences were small and dependent on the definition of nocturnal hypoglycaemia. Similar results had been observed for type 1 diabetic patients in terms of non-inferiority to insulin glargine. Mr Dhadli advised that the annual cost of U-500 insulin was in the region of £1,300 and the cost of degludec was £2,600 for 150 units per day of insulin. **Agreed:** Degludec U100 classified as a **BROWN specialist initiation** drug for patients with documented nocturnal hypoglycaemia being considered for insulin pumps and degludec U200 as a **BROWN specialist initiation** drug for patients where U-500 insulin is being considered.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**<u>Asthma Guidelines</u>** Mrs Qureshi advised JAPC that the adult asthma guidance had been updated with the MART strategy alongside SMART this advocates the use of fostair for single maintenance and reliever therapy in a carefully selected patient group. Mr Dhadli stated that this approach has been supported by NICE and a DTB review. Dr Henn queried the inclusion of the statement 'adjust according to theophylline levels' for the additional therapy six week sequential therapeutic trial of uniphyllin 200mg twice a day. It was agreed that this statement would be removed from the guidance. Dr Shearer referred to the various versions of asthma guidance and the potential for confusion for GPs which could be caused. Mr Dhadli confirmed that the local guidance was based on BTS and SIGN guidance and with Derbyshire formulary drug choices included. Dr Parkin queried the recommendation in step 2 to use clenil modulate MDI 100mcg in preference to QVAR MDI 50mcg although QVAR was recommended in step 3(c). Mrs Qureshi stated that this was based on cost effectiveness. Dr Henn highlighted that the guidance gave clinicians information about drug costs and the different strengths of drugs. **Agreed:** JAPC ratified the adult asthma guidance with the agreed amendment. Mrs Qureshi reported that the children's asthma guidance is a new guideline. Various updates to a draft had been to a number of forums and comments received from the respiratory clinicians at RDH and CRH. Mrs Qureshi highlighted that the Guidelines Group had extensively discussed the use of fluticasone, which did not currently have a traffic light classification, but that seretide had been	**SQ** **SQ**

	included at step 3, by request from respiratory clinicians. During discussion Mrs Needham stated that the majority of children would be at steps 1 and 2 in the guidance and that the discussions had focussed on the inclusion of multiple drugs at step 3. Mrs Qureshi commented that it would have been advantageous to include fostair in step 3 but this did not have a licence for use in children and so the move to seretide or symbicort, as a combination inhaler, at step 3 was included. Mr Newman referred to the advice received from Dr Carroll, RDH respiratory consultant, that combination therapy was needed at step 3 in preference to the use of separate components, especially LABAs which had been associated with asthma deaths. Dr Tooley also commented on the potential safety and compliance concerns associated with the recommended use of the three separate inhalers at step 3(a) in the guidance. It was agreed that the references to the use of salbutamol + clenil + formoterol and the one month trial of a LABA in step 3(a) be deleted. Dr Fitzsimons queried the inclusion of spacers and Mrs Qureshi referred to the recommended use of a metered dose inhaler (MDI) plus a spacer device on the last page of the guidance. Mr Newman stated that Dr Carroll had commented that the recommended use of spacer devices be highlighted in step 1. Mrs Qureshi would include a reference to the use of spacers in step 1. **Agreed:** JAPC ratified the children's asthma guidance with the agreed amendments.	**SQ** **SQ** **SD**
b.	**<u>Management of Overactive Bladder (OAB)</u>** Mr Dhadli reported that a NICE TA review in June 2013 had recommended the use of mirabegron as a treatment option for the management of people with OAB. JAPC had previously discussed mirabegron and it had been agreed that a pathway be developed for use of mirabegron with the various treatment options for the primary care management of OAB. Feedback had been received from the CRH urologists who had indicated that they did not recommend the use of oxybutynin due to side effects with dry mouth and had suggested the use of tolterodine first line. Mr Newman reported that a RDH gynaecology consultant had reviewed the pathway as part of the mirabegron submission to the RDH Drugs and Therapeutic Committee. One of the comments received had highlighted that the use of mirabegron reduced but did not avoid anticholinergic side effects. Mr Dhadli added that various reviews had revealed mirabegron had limited long term efficacy data and that the twelve month studies did not highlight any major safety issues. Mirabegron lacks direct head to head clinical studies, whilst tolerodine was included as an active control, the trials were not designed to compare tolterodine and mirabegron. The evidence is derived from short term studies. **Agreed:** Oxybutynin classified as 1st line choice, tolterodine 2nd line choice. Trospium, darifenacin, fesoterodine, mirabegron and solifenacin classified as GREEN 3rd line options for the management of OAB. Clinical pathway agreed.	**SD**
c.	**<u>Prevention of Stroke and Systemic Embolism in Atrial Fibrillation (AF) with Warfarin and New Oral Anticoagulants (NOACs)</u>** Mr Dhadli reported that, following publication of NICE TA 275 which had recommended the use of apixaban for the prevention of stroke and systemic embolism in people with nonvalvular AF, both documents had been updated to	

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	include therapeutic details for apixaban. Comments had been received from Dr McKernan which had been included in the guidance. Dr Mott queried whether rivaroxaban, dabigatran and apixaban should be listed as 1st, 2nd and 3rd line drugs in the guidance taking into consideration reversibility factors and contra-indications. This would be discussed further at a meeting to include Dr McKernan, RDH Consultant Haematologist.	**AM**
	Agreed: JAPC ratified the guidance but would be brought back for further consideration if necessary.	**SD**
d.	**<u>Guidelines for the Management of Neuropathic Pain (NeP) in Primary Care</u>** Mr Dhadli reported that the guidelines had been brought back for further discussion due to concerns about morphine use in NeP and non-malignant chronic pain management. Mr Dhadli highlighted the main changes which had been made in the guideline: • The maximum dose of morphine had been changed to 120mg to align this with the chronic pain guidelines. • The use of modified release morphine. • Pregabalin had been included as a treatment option as per current traffic light classification. • Duloxetine included stating already agreed traffic light classification, 3rd line option for NeP after specialist initiation.	
	Dr Game reported that Dr Faleiro, RDH Pain Management Consultant, had commented on the use of the term enigmatic to describe NeP in the introduction to the guidelines. Dr Faleiro had suggested that this should be re-written. Further comments had been made that NeP was thought to affect 8% of the general population rather than 2-4% and that referral to specialist teams should be included in the table on page 3. Dr Game would send the comments made by Dr Faleiro to Mr Dhadli.	**FG**
	Dr Mott commented that duloxetine should be included in the table on page 3. It was agreed that duloxetine be included in the table.	**SD**
	Agreed: JAPC ratified the guidelines for the management of neuropathic pain in primary care.	**SD**
e.	**<u>Guidelines for Chronic Pain Management in Primary Care</u>** Mr Dhadli stated that the June JAPC meeting had agreed amendments to be made to the guidelines for chronic pain management in primary care. Further comments from the pain consultants included: • More treatment and pain management options should be included. • Referral to specialist should be considered if patients were to be started on morphine- JAPC agreed • Treatment options to include buprenorphine patches and targinact - JAPC does not support the use of these products and prescribers should continue to follow current traffic light classification • The use of nefopam was not advised. JAPC noted this but considered this appropriate in a primary care setting. • There should be testosterone monitoring in long-term opioid users. Mr Dhadli stated that the advice from the British Pain Society's 'opioids for	

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	persistent pain- Good practice' guide offered sensible pragmatic advice. Endocrine function should be monitored regularly if symptomatically indicated and referred to an endocrinologist where necessary Dr Tooley commented that the statement that referral to a pain clinic should be carefully considered before starting patients on strong opioids should be highlighted in the guidance. Mr Dhadli would include a further statement on page 3. **Agreed:** JAPC ratified the guidelines for chronic pain management in primary care with the agreed amendments.	**SD** **SD**
f.	**North Derbyshire CCG Acne Pathway** Mrs Needham outlined the main changes which had been made to the pathway and informed JAPC that the training for the dermatology champions which would include education and training for the North Derbyshire CCG GPs was to take place next week. **Agreed:** JAPC ratified the Acne Pathway on behalf of NDCCG.	**SD**
g.	**Emollient Prescribing** **Agreed**: JAPC ratified the emollient prescribing guide.	**SD**
h.	**Glucose Control in Type 2 Diabetes** Mr Dhadli stated that that local guidance had been updated to include the decisions which had already been made for lixisenatide in support of the shared care agreement and diabetes trained clinicians and dapagliflozin. **Agreed:** JAPC ratified the glucose control in type 2 diabetes guidelines.	**SD**
8.	**PATIENT GROUP DIRECTIONS (PGDs)**	
a.	**Shingles** Mr Hulme reported that this was a new PGD which had been written by the Nottingham Medicines Management Team on behalf of the Public Health England Derbyshire and Nottinghamshire Area Team in line with the national shingles vaccination programme for this year. Discussion followed about the governance arrangements for PGDs and whether they would need to be signed-off by the CCG Boards. Dr Bell queried whether JAPC were able to approve these as they were signed off by the Area Team. Mr Steward commented that the clinical content of PGDs usually required sign-off by a clinician or pharmacist and further sign-off for governance reasons by the organisation which employed the staff who would be using the PGDs. Mr Newman highlighted the increasing number of vaccine errors and queried whether a reference to the administration of Zostavax, which was the only shingles vaccine with marketing authorisation available in the UK, be included in the PGD. JAPC approved the shingles PGD and it was agreed that all future PGDs should be presented to JAPC for information.	**SD**

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9.	**SHARED CARE GUIDELINE**	
a.	**Degarelix** Mr Dhadli reported that in January 2013 there had been a proposal made by RDH for use of degarelix in advanced hormone-dependent prostate cancer and an immediate clinical need for rapid lowering of testosterone in a small number of high risk patients. RDH had therefore requested that degarelix, which was administered by monthly injection, be used in three different groups of patients with the following indications: • Impending spinal cord compression. • Renal failure due to ureteric obstruction. • Severe symptoms warranting hospitalisation. Mr Dhadli stated that JAPC had agreed to look at the first two of the above indications in terms of a shared care agreement. It did not approve the third indication. During discussion Mrs Needham stated that the drug was not supplied to practices so prescriptions had to be written for collection by patients. Mrs Needham suggested that this should be highlighted in the list of patient responsibilities and that, in cases of missed doses, a referral to hospital should be made. Dr Mott commented that it needed to be determined whether there was a place for degarelix and highlighted considerable problems with the implementation. **Agreed:** JAPC postponed classifying degarelix until the implementation process had been ironed out **Action:** Degarelix remains classified red until the traffic light classification for degarelix would be assigned when details of the implementation were available and for only the two indications of: • Impending spinal cord compression. • Renal failure due to ureteric obstruction.	**SD** **SD**
10.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches and new drug formulations: Ivacaftor – JAPC already classified as RED. Pirfenidone – JAPC already classified as RED. Fluocinolone intravitreal implant – JAPC already classified as BLACK. Potassium hydroxide solution 5% - Potentially large group of patients for the self-limiting condition of molluscum contagiosum lesions Mr Dhadli would bring further information on the treatments for the next JAPC meeting. Naloxone injection – To be left as unclassified awaiting request for its use. Colistimethate sodium dry powder inhaler – JAPC already classified as RED. Soybean oil eye drops – Potential requests for use for the treatment of dry eyes. Mr Dhadli would bring a review of the evidence to the next JAPC meeting.	**SD** **SD** **SD**

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	Water soluble vitamins for renal patients – To be left as unclassified awaiting request for use.	**SD**
11.	**MISCELLANEOUS**	
a.	**Niquitin** JAPC agreed the use of Niquitin strips as third line in the formulary.	**SD**
b.	**CONTACT Study** Mr Dhadli referred to the discussion at the last JAPC meeting about excess treatment costs and the advice to be offered by JAPC to CCGs on the drugs included in trials in order to highlight risks to prescribing budgets and deviation from locally agreed guidelines and pathways. Mr Dhadli outlined the five questions to be addressed by JAPC on the CONTACT (Colchicine Or Naproxen treatment for Acute gouT) study together with the responses: • Is the drug on the preferred formulary? Naproxen and colchicine were in the preferred formulary chapter. • What is the financial risk to the CCGs during and on completion of the trial? The financial risk was minimal. • Will prescribing of this drug influence GP prescribing outside the clinical trial? No. • Are there any clinical concerns that will undermine local prescribing advice? No • Does the trial conflict with the CCGs strategic position/direction? No. The CCG Leads would feedback these responses to the CCGs.	**CCG Leads**
c.	**Melatonin** Mr Dhadli stated that JAPC had agreed at the March 2013 meeting that Circadin MR should be the 1st line choice of melatonin for the treatment of sleep disorders in children with neurodevelopmental disorders and that the shared care guideline be extended to September 2013 to allow for the transition of patients to this licensed product. Following the switch to Circadin the shared care would be re-written as a supporting information document. Mrs Needham highlighted that the declassification of shared care had been to brown specialist initiation not green specialist initiation and this would be amended in the supporting paper. Mr Dhadli explained that the following additions would be made to the information sheet: • Inclusion of a key contact list including details of specialists from RDH and CAMHS. • Inclusion of the NICE review of sleep disorders for melatonin with ADHD. • Circadin MR was classified as brown specialist initiation for children but its use for the licensed indication for patients over 55 was not recommended. • Other melatonin products were unlicensed except Circadin MR. • The maximum dose would be added. Mr Dhadli referred to a meeting with DHcFT consultant paediatricians who had supported the use of immediate release melatonin products for small cohorts of patients. Dr Taylor would check the views of the consultant paediatricians and report back to the next meeting.	**SD** **ST**

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12.	**JAPC BULLETIN**	
	It was agreed that it should be highlighted that Zostavax is the only vaccine licensed for use in the national shingles vaccination programme. The amended JAPC bulletin was ratified by JAPC.	**SD**
13.	**MHRA DRUG SAFETY UPDATES**	
	The MHRA Drug Safety Update for August 2013 was noted. Mr Dhadli highlighted the following MHRA advice: Caffeine (citrate) for apnoea of prematurity – JAPC agreed that caffeine (citrate) be classified as a **RED** drug. Nitrofurantoin for urinary tract infections was contraindicated in patients with <60mL/min creatinine clearance. Mr Dhadli stated that the UTI guidance and antimicrobial guidance had been updated accordingly. It was queried whether the safety guidance referred to creatinine clearance or eFGR and the risk of confusion about this was highlighted. Mr Dhadli would contact Dr Diane Harris, Specialist Antimicrobial Pharmacist, to clarify this. Oral ketoconazole should no longer be prescribed for fungal infections as the risk of liver injury outweighed benefits – JAPC had previously classified this as a red drug under DLCV. Metoclopramide risk of neurological adverse effects – The maximum dosage should be 30 mg and treatment should be for no longer than five days. The local formulary chapter had been updated to reflect this. Dr Game commented that occasional patients under palliative care or with gastroparesis may be on this drug longer term. Mr Newman stated that RDH had a new tracking system to deal with the drug safety alerts and as part of this would check on usage of the drug in palliative care with the consultants and report back to the October JAPC meeting.	**SD** **SD** **CN**
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in August: TA295 Everolimus in combination with exemestane was not recommended for treating advanced HER2-negative hormone-receptor positive breast cancer after endocrine therapy. Everolimus classified as a **BLACK** drug. CG169 Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. The CG recommended consideration of the use of electronic systems to support clinical decision-making and prescribing. If such systems were procured there would be a cost impact for secondary care but not primary care. CG170 Autism: the management and support of children and young people on the autism spectrum. There were no cost implications for primary care.	**SD**

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15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Degludec (100units/ml and 200units/ml)– BROWN specialist initiation according to specified criteria Trospium – GREEN 3rd line Darifenacin – GREEN 3rd line Fesoterodine – GREEN 3rd line Mirabegron – GREEN 3rd line Solifenacin – GREEN 3rd line Caffeine (citrate) – RED Everolimus as per TA295 – BLACK	
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Shared Care Disulfiram – Still waiting for clarity on medically managed and monitoring requirements in first six months. Transgender Prescribing – Mr Dhadli would find out more about any national guidance. Seretide – To be removed from the list. Apixaban – This had been dealt with during the discussion about the NOAC guidelines and would therefore be removed from the list. Melatonin as Circadin MR is now supported by an information sheet as well as a temporary shared care agreement. Awaiting comments from community paediatricians. To come back October 2013. Opioid Pain Guidance/Neuropathic Pain guidance – To be removed from the list. Mirabegron NICE TA 290 – To be removed from the list.	**SD** **SD** **SD** **SD** **SD** **SD** **SD**
17.	**GUIDELINE GROUP**	
	The Guideline Group action tracker was ratified by the JAPC.	**SD**
18.	**ANY OTHER BUSINESS**	
	No items of any other business were transacted.	
19.	**DATE OF NEXT MEETING**	
	Tuesday, 8 October 2013 in the Post Mill Centre, South Normanton.	