For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 13 August 2013

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Epilepsy core formulary (clonazepam, carbamazepine, ethosuximide, gabapentin, pregabalin, lacosamide, lamotrigine, levatiracetam, oxycarbazepine, phenobarbital and other barbiturates, phenytoin, topiramate, valproate, zonisamide)	GREEN specialist initiation
Epilepsy (eslicarbazepine, perampanel, retigabine, rufinamide, stiripentol, tiagabine, vigabatrin)	RED
Dapagliflozin	BROWN following specialist initiation
Pentoxyfilline	BLACK
Zostavax	BLACK
Probiotics	BLACK
Aripiprazole	RED for use in people under 18 years of age
Eltrombopag	RED
Aflibercept	RED

Clinical Guidelines

Management of Clostridium Difficile
Oral Thrush
Antipsychotics – Recommended Physical Monitoring

Shared Care Guidelines

Acetycholinesterate Inhibitors
Liothyronine

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

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
Mrs L Hunter	Assistant Chief Finance Officer
Dr A Mott	GP (also representing Erewash CCG for this meeting)
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
Derby Hospitals NHS Foundation Trust	
Dr F Game	Chair – Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Mr D Branford	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Trust	
Mr M Steward	Chief Pharmacist
Lay Representative	
Dr C Shearer	Healthwatch Derbyshire

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

Item		Action
1.	**APOLOGIES**	
	Dr M Henn and Dr I Tooley.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Rivaroxaban for PE • Coagucheck • Excess Treatment Costs • JAPC Terms of Reference	
4.	**MINUTES OF JAPC MEETING HELD ON 9 JULY 2013**	
	The minutes of the meeting held on 9 July 2013 were agreed as a correct record with the following amendments: Reflectant Sunscreen Cream (Dundee Cream) – Addition of costs for community pharmacists as per tariff. CG164 Familial Breast Cancer – Amend to: Prescribing would commence in secondary care and then move out to primary care.	
5.	**MATTERS ARISING**	
a.	**Guidelines Sub-Group Terms of Reference** 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 agendas.	
b.	**High Cost Drugs** Mr Newman reported that Suzanna Taylor from NHS England had indicated that a plan, which would include overall patient numbers, would be developed by April 2014.	
6.	**NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS**	
a.	**Epilepsy** Mr Dhadli stated that, due to the lack of an agreed formulary across Derbyshire and new launches of significantly more expensive drugs, a review had been undertaken of the traffic light status used by Nottingham, Sheffield and Manchester which had revealed regional variations in the traffic light classification of the drugs. A core formulary had therefore been developed of drugs classified as green following specialist initiation. A further list had been developed of seven drugs which should only be considered in line with the recommendations of the tertiary centres and had been appropriately traffic lighted by the host area prescribing committee. Discussion followed and it was highlighted that the second range of drugs needed a specific proposal for Derbyshire to re-classify from red, and that there was quite a lot of usage of vigabatrin in primary care. **Agreed:** JAPC approved the core formulary of green drugs following specialist initiation.	**SD**

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

Item		Action
	Agreed: The seven other drugs to be classified as **RED** drugs and the recommendation of the respective APC where the tertiary centre was based should be accepted in the event of out of area non-formulary requests. This would be included in the traffic light database together with a statement about initiation from either secondary care or a tertiary centre. The Derbyshire formulary section would include a link to the APC's medicines management website.	**SD**
b.	**Dapagliflozin** Mr Dhadli reported that the July JAPC meeting had classified dapagliflozin as brown after specialist initiation based on the NICE TA 288. However, in order for it to be included in the primary care formulary, it would be necessary to review the evidence as a new drugs assessment using the JAPC framework. Dapagliflozin was a SGLT2 inhibitor which lowered plasma glucose by inhibiting the renal re-absorption of glucose and promoting its urinary excretion. There had been eight fully published multicentred phase III RCTs which had assessed the efficacy and safety of dapagliflozin and this had demonstrated strong evidence in reducing HbA1c. Seven of these trials had been used as a placebo comparator and the eighth had been an active comparator trial. Mr Dhadli highlighted that the FDA had requested additional data to allow further assessment of the benefit-risk profile concerning a higher incidence of breast and bladder cancers reported in patients treated with dapagliflozin. Its use for patients with EGFR <60 was not recommended. 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. Mrs Hunter queried the number of patients involved and was informed that it would probably affect a very small number due to low usage. **Agreed:** Dapagliflozin classified confirmed from previous months decions as a **BROWN** following specialist initiation drug.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**Acne Pathway** Mrs Needham reported that North Derbyshire CCG were currently working on dermatology referrals as part of the QoF QP work for 2013 - 2014 and this involved the development of an acne pathway to reduce and improve the appropriateness of referrals to secondary care. Dermatology champion meetings would be held in September to provide education and training to the GPs. Dr Diane Harris had provided feedback on the antimicrobial content and this had been sent to the GPs who had developed the pathway for comment and agreement. Mr Dhadli queried the section in page 4 which referred to doubling the dose of doxycycline and the use of trimethoprim. It was agreed that further discussions about the antibiotics should take place outside the meeting and that the whole pathway did not need to be changed. **Action:** Mrs Needham would bring the revised document to the September JAPC meeting prior to use at the GP September training events.	**KN**
b.	**Clostridium Difficile** Mr Dhadli reported that Dr Diane Harris, CCG Specialist Antimicrobial Pharmacist,	

Item		Action
	had been contacted by a microbiologist at RDH in connection with the section in the Guidance on the Management of C Difficile Infection (CDI) in Primary Care which referred to the agreement for microbiologists to be contacted by GPs for advice on treating first recurrence of CDI. The microbiologist had indicated that it was not necessary for them to be routinely contacted unless the CDI was severe or there were other clinical reasons. Dr Harris had subsequently contacted the lead author of the new national C Difficile guidance for advice on treating first recurrence and advice had been received to use vancomycin 125mg six hourly for 10 to 14 days. The guidance had therefore been changed to reflect this advice. Mr Dhadli also referred to a recommendation from a microbiologist for the use of fidaxomycin for some patients. It was highlighted that fidaxomicin was non-formulary and therefore a paper would be needed for consideration by JAPC. Mr Dhadli also highlighted the statement concerning recurrence within 28 days in the referral section of the guidance. It was agreed that, in order to achieve consistency throughout the document, this statement should be removed from the guidance. **Agreed:** JAPC ratified the changes to the Guidance on the Management of C Difficile Infection in Primary Care.	**DH** **SD**
c.	**<u>Oral Thrush</u>** Mr Dhadli advised JAPC that a position statement had been prepared by Ms Helen Dean, RDH Infant Feeding Specialist, which provided Independent Prescribers (Medical or Non-Medical) with the evidence to treat thrush effectively and enable mothers to continue to breastfeed. The most effective medication for the treatment of surface and ductal thrush in the infant remained off-licence. The guidance had therefore been updated and some additional items included. Mr Dhadli highlighted that page 6 referred to the use of miconazole for two weeks by Independent Prescribers and for ten days by community practitioners and nurse prescribers. During discussion it was highlighted that the guidance should be amended to make clear what was needed in each particular situation. Dr Bell stated that it was unclear whether the guidance had involved representation from all health care professionals including Derbyshire Community Health Services. Dr Fitzsimons commented that community practitioners and nurse prescribers should contact the Independent Prescriber or follow the PGD to supply medicine if this was available as an option. A decision should be made as to whether to follow a PGD or whether the Independent Prescriber should be contacted for the prescription of miconazole. It would also be necessary to clarify the reference to the use of a black swan tube and that 'under 28 days' should be removed from the title of the guidance. **Agreed:** JAPC ratified the guidance with the agreed amendments. **Action:** The guidance would be circulated to the DCHS Health Visitor Managers for comment.	**HD** **SD** **MS**
d.	**<u>Antipsychotics – Recommended Physical Monitoring</u>** Mr Branford highlighted the main changes in the updated clinical guideline for	

Item		Action
	physical health care screening for patients prescribed antipsychotics: • Lipids added at monitoring at three months and annually. • Recommendation for U and E, LFT and FBC at three and six months removed. • Check cholesterol in annual monitoring amended to cardiovascular risk assessment. • ECG baseline for all patients. • The reference to checks for cough and sputum had been deleted as there was an expectation that this would form part of the questions about smoking status. Dr Parkin reported that a number of meetings about ECG monitoring had been held within Hardwick CCG as lead commissioners for mental health care services. It had been concluded that secondary care was funded to undertake ECGs which were necessary and additional funding provided for this. It was noted that the guidance had taken ECG responsibility away from primary care. Dr Shearer referred to the need for the smoking cessation service to proactively intervene. **Agreed:** JAPC ratified the clinical guideline for antipsychotics physical monitoring.	**SD**
8.	**SHARED CARE GUIDELINES**	
a.	**Lixisenatide** Dr Game stated that the existing shared care guidance had been updated with the inclusion of lixisenatide as a first line GLP-1 agonist to replace exenatide for new starters. The traffic light classifications for both lixisenatide and exenatide would be green for specially trained staff and amber for non-trained staff. Mrs Needham stated that the responses concerning loss of weight and HBA1c achievement should be included in all the flowcharts rather than as a separate footnote, and a Derbyshire letter would be developed concerning patient targets. Mrs Needham would send a draft letter to Dr Game for possible Derbyshire-wide use. Dr Bell highlighted that the reference to continued use of the drug only if beneficial had been omitted from the lixisenatide guidance. Dr Game agreed to include this together with an update of diabetes guidance in the patient responsibilities section. The need for training would also be discussed outside the meeting and the position of liraglutide as second line confirmed in the flowchart. **Agreed:** The shared care guidance for GLP1 agonists in the treatment of type 2 diabetes was ratified by JAPC.	**KN** **FG** **SD**
b.	**Acetylcholinesterase inhibitors** Mr Branford reported that the shared care agreement had been made more explicit to include the need for an annual review and an annual physical health check. Mr Dhadli added that renal and hepatic advice had been included in the monitoring requirements together with a reference to adverse effects. Dr Mott referred to discussions about whether shared care was needed for this group of drugs. Mr Dhadli commented that the shared care originated from a NICE	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

Item		Action
	TA in 2007 which referred to a six monthly review. **Agreed:** JAPC ratified the acetylcholinesterase shared care guideline.	**SD**
c.	**Liothyronine** Mr Branford reported that the liothyronine shared care guidance had been re-worded to remove the requirement for ECG monitoring. Dr Game advised that the title should be amended to indicate that liothyronine was for the treatment of persistent depression. **Agreed:** JAPC ratified the liothyronine shared care guideline.	**SD**
9.	**MISCELLANEOUS**	
a.	**Shingles Vaccine – Zostavax** Mr Dhadli reported that the shingles vaccine would be offered to people aged 70 years from September 2013. A catch-up campaign would be operated which would offer vaccination to anyone aged up to 79 years old although it was not recommended for people aged 80 years or over. Mr Dhadli added that JAPC had previously classified zostavax, which was the only shingles vaccine with market authorisation available in the UK, as black in July 2013. **Agreed:** Zostavax classified as a **BLACK** drug unless as part of the national immunisation campaign.	**SD**
b.	**Pentoxyfilline** Mr Steward stated that comments had now been received from the specialists regarding pentoxyfilline for healing venous leg ulcers which had been previously discussed by JAPC in the light of a request for clarity from a GP on its traffic light classification. JAPC was advised that a Cochrane review had recommended its use and Mr Hulme commented that there were some drugs in use which were classified as black. **Agreed:** Pentoxyfilline for healing venous leg ulcers was not used in Derbyshire used and therefore classified as a **BLACK** drug.	**SD**
c.	**Biogaia Probiotic Drops** Mrs Needham reported that a GP had been requested to prescribe biogaia probiotic drops for a 21 month old child. A Sheffield Children's Hospital consultant had discharged this patient and asked the GP to prescribe. Biogaia probiotic drops were not listed in the BNF as it was a dietary supplement and not a licensed medicine. Mr Dhadli referred to a Cochrane review which had supported the use of probiotics as a treatment for acute infectious diarrhoea but had highlighted marked clinical variability in the studies. **Agreed:** Biogaia and all other probiotic drops (excluding VSL 3) were classified as **BLACK** drugs.	**SD**
d.	**Linaclotide MTRAC Review** The Midlands Therapeutics Review and Advisory Committee (MTRAC) commissioning guidance on linaclotide for the treatment of irritable bowel syndrome with constipation was noted by JAPC.	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

Item		Action
10.	**JAPC BULLETIN**	
	The amended JAPC bulletin was ratified by JAPC.	
11.	**MHRA DRUG SAFETY UPDATES**	
	The MHRA Drug Safety Update for July 2013 was noted. Mr Dhadli highlighted the following MHRA advice: Codeine for analgesia – Codeine should now only be used to relieve acute moderate pain in children older than 12 years and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen alone. A significant risk of serious and life-threatening adverse reactions had been identified in children with obstructive sleep apnoea who received codeine after tonsillectomy or adenoidectomy or both. Mr Dhadli added that the formulary chapter had been updated accordingly to reflect this new advice.	
12.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in July: TA 297 Aripiprazole for treating moderate to severe manic episodes in adolescents with bipolar disorder. Aripiprazole oral tablets were previously classified as green following consultant recommendation and IV as red. NICE had estimated that bipolar disorder affected between 0.5% and 0.6% of the population and a very small proportion of this would be adolescents. The prescribing of aripiprazole for adolescents had been off-licence until January 2013 when the licence had been extended. There may consequently be an increase in adolescent patient numbers of between 15 and 25 % but NICE did not predict a significant impact on NHS resources. Aripiprazole classified as a **RED** drug for use in adolescents. TA 293 Eltrombopag for treating chronic immune (idiopathic) thrombocytopenic purpura (review of technology appraisal 205). NICE did not predict a significant change in resources as this drug was just an alternative with a very small numbers of patients. Eltrombopag classified a **RED** drug. TA 294 Aflibercept for macular degeneration (wet age-related). This was an alternative drug to lucentis and required less frequent administration to give similar clinical outcomes. NICE had assumed that 30% of patients would take up aflibercept compared to lucentis and had produced a costings template which revealed cost savings of approximately £10K for Hardwick and Erewash CCGs, £52K for South Derbyshire CCG and £33K for North Derbyshire CCG. The drug came with a patient access scheme which reduced the price quite significantly. Aflibercept classified as a **RED** drug. CG Myocardial infarction with ST-segment elevation.	**SD** **SD** **SD**

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

Item		Action
	CG 168 Varicose Veins in the Legs: The diagnosis and management of varicose veins. A statement about the clinical guideline would be placed in the bulletin.	**SD**
13.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Epilepsy – GREEN list Epilepsy – RED list Dapagliflozin – BROWN following specialist initiation Pentoxyfilline – BLACK Zostavax – BLACK Probiotics – BLACK Apriparazole – RED for use in people under 18 years of age. Eltrombopag – RED Aflibercept – RED	
14.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Shared Care Disulfiram – Mr Branford would contact Ms Caroline Jones (DHcFT) about the update of the guidance in accordance with JAPC recommendations. Seretide – To be brought to the September JAPC meeting. Apixaban – To be brought to the September JAPC meeting. Actinic Keratosis – To be brought to the September JAPC meeting. Mirabegron – To be brought to the September JAPC meeting. Diabetes Guidelines – Dr Game to be invited to a meeting of the Guidelines Group.	**DB** **SQ** **SD** **SD** **SD** **KN**
15.	**GUIDELINE GROUP**	
	The Guideline Group action tracker was ratified by the JAPC.	**SD**
16.	**MINUTES OF OTHER PRESCRIBING GROUPS FOR INFORMATION**	
	• STAMP 11/6/13 • Burton Drugs and Therapeutic Committee 8/7/13 (draft) • Derbyshire Healthcare Foundation Trust Drugs and Therapeutic Committee 27/6/13 (draft) • Sheffield Area Prescribing Group 18.6.13 • MOST (DCHS) 10/7/13	
17.	**ANY OTHER BUSINESS**	
a.	**Rivaroxaban for Pulmonary Embolism** Rivaroxaban for Pulmonary Embolism classified as a **GREEN specialist initiation** drug.	**SD**
b.	**Coagucheck** Dr Mott stated that coagucheck testing had been requested for children with complex needs including congenital heart problems in the home setting rather than	

For agenda items contact Slakahan Dhadli
Tel: 01332 868781
Email: slakahan.dhadli@southernderbyshireccg.nhs.uk

Item		Action
	in existing patient services. JAPC had previously classified the coagucheck strips as brown due to the different services provided in the city and county. The machines could be self-funded and the strips prescribed from GP budgets. Dr Mott added that a request had not been made to re-classify coagucheck but it would be necessary to determine how the children accessed this and whether this group of children came into the definition of exceptionality. Mr Dhadli advised that the cost of the meters was £350 and the strips £67 x 24 and £131 the next size up and it would need to be highlighted to the CCGs that they may need to fund these in the future. The dosing was undertaken by secondary care. Mr Hulme highlighted the need for the meters to be properly calibrated and queried whether the strips could be obtained from other sources such as the Kite team. The exceptionality needed to be very specific and what was in the service level agreement with the Kite team.	
c.	**Excess Treatment Costs** Dr Parkin stated that as part of their constitution the CCGs had responsibility to encourage practices to enter into research. There were two categories of research; industry research where the drugs were provided and NIHR approved trials where the NHS had responsibility for picking up the costs of the drugs involved. Dr Game commented that this was not an issue for the Ethics Committee but rather research and development and there were research costs and excess treatment costs. Dr Bell highlighted that the CCGs needed to make the decisions as to whether to participate in trials but JAPC could offer advice to CCGs as to how they fitted in with local policy. It should be clear that when CCGs made a decision any conflicts of interest should be declared. The financial risks for CCGs should also be made very clear and it was important that GP prescribing should not be influenced.	
d.	**JAPC Terms of Reference** Dr Bell requested that the CCG representatives chase up comments on the previously circulated JAPC revised terms of reference.	**CCG leads**
18.	**DATE OF NEXT MEETING**	
	Tuesday, 10 September 2013 in the Post Mill Centre, South Normanton.	