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 12 November 2013

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Raloxifene	GREEN 2nd line after Consultant Initiation for familial breast cancer in postmenopausal women where tamoxifen is poorly tolerated or considered inappropriate (see NICE CG164)
Propiverine	GREEN 3rd line after trial of oxybutynin and tolterodine
Duloxetine	GREEN 3rd line after trial of oxybutynin and tolterodine and surgery not suitable
Ocriplasmin	RED as per NICE TA297 for treating vitreomacular traction

Clinical Guideline

Primary Care Management of Overactive Bladder – Updated with NICE CG171

Shared Care Guideline

Riluzole for the treatment of the Amyotrophic Lateral Sclerosis form of Motor Neurone Disease

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
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	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Trust	
Ms C Curry	Principal Pharmacist
Lay Representative	
Dr C Shearer	Healthwatch Derbyshire
In attendance	
Ms S Azam Ms L Ricketts Mr A Thorpe	Pharmacist, Southern Derbyshire CCG Pharmacist, Southern Derbyshire CCG Derby City Council Public Health

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

Item		Action
1.	**APOLOGIES**	
	Mr M Steward.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of conflict of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Molludab. • Guidelines Group Terms of Reference Update. • Indapamide in hypertension.	
4.	**MINUTES OF JAPC MEETING HELD ON 8 OCTOBER 2013**	
	The minutes of the meeting held on 8 October 2013 were agreed as a correct record.	
5.	**MATTERS ARISING**	
a.	**Metoclopramide** Mr Newman reported that a draft statement was being prepared to back up the position of the palliative care consultants that metoclopramide could be a useful agent in particular situations. This statement would be brought to the next meeting.	**CN**
b.	**Renavit** Mrs Needham advised that Renavit could be obtained from Unichem without incurring out of pocket expenses.	
c.	**Nitrofurantoin** *Mr Newman reported that the RDH Antimicrobial Group was working on the statement concerning renal function for inclusion in the JAPC bulletin. Mr Dhadli referred to the issue concerning eGFR which was not considered to be a good predictor for creatinine clearance. There was some supporting evidence to suggest a creatinine clearance between 60 – 40mll/min may be preferred over the contraindication of <60ml/min creatinine clearance which had been stated in the September MHRA Drug Safety Update. Mr Shepherd highlighted the potential confusion which could be caused by conflicting advice given in the British National Formulary and by JAPC.*	
6.	**NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS**	
a.	**Raloxifene** Mr Dhadli stated that raloxifene (and tamoxifen) were included as options for women at risk of familial breast cancer, NICE CG 164, but had not been assigned a traffic light classification by JAPC. The guideline recommended raloxifene as an option for postmenopausal women where tamoxifen was poorly tolerated or not considered appropriate. **Agreed:** Raloxifene classified as **GREEN 2nd line option** for familial breast cancer after consultant initiation where tamoxifen is poorly tolerated or considered inappropriate (NICE CG164).	**SD**

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

b.	**Dutasteride and Combodart** *Mr Dhadli reported that prescribing requests to primary care have been received from secondary care to use dutasteride for the treatment of benign prostatic hyperplasia (BPH). RDH has both finasteride and dutasteride in their appropriate formulary chapter but the JAPC Derbyshire wide formulary includes finasteride only. Both dutasteride and Combodart (a combination product containing dutasteride) have not been assigned a traffic light classification. The annual costs in Derbyshire was £194,000 for 51,286 items of dutasteride 500mg, finasteride 5mg £75,000 for 34,875 items and Combodart (a combination treatment of dutasteride plus tamsulosin) £32,980 of 1,338 items.* Mr Dhadli investigated the submission at RDH and discovered that for formulary inclusion made in 2007 was at a time when the cost differential between dutasteride and finasteride was small and it had been estimated ten new patients a year, and for use to continue in primary care. The evidence submitted at the time to the RDH Drugs and Therapeutic Committee had come from the SMC and London New Drugs Group who had recommended both dutasteride and finasteride, again at a time when the cost difference was small. A further review by RDH in 2010 then looked at the combination treatment of Combodart. Neither of these drugs were submitted to JAPC. Mr Dhadli informed JAPC that the evidence review submitted to RDH at the time of consideration was when the cost differential between finasteride and dutasteride was minimal. Since then the price of finasteride has fallen significantly. JAPC were informed that the European Association of Urology guidance 2013 have no preferred drug stated. A 2005 Canadian health technology appraisal recommended dutasteride be listed in a similar way to finasteride (time when costs were the same). NICE CG 97 2010 made no recommendation of a preferred product in relation to LUTS. During discussion Mr Dhadli stated that the views of the consultant urologists had been requested but these had not been received as yet. The RDH Drugs and Therapeutic Committee had agreed that Combodart be approved for inclusion in the Trust formulary and then be forwarded to JAPC for possible inclusion on the Derbyshire formulary as green specialist initiation. It was highlighted that this combination was significantly more expensive than tamsulosin plus finasteride and that NICE CG 97 did not recommend a preferred combination or product. Mrs Needham commented that in the north the preferred drug of choice was finasteride and that successful switches have been made from dutasteride to finasteride in primary care over the past eighteen months. Dr Game confirmed that finasteride was also the first line choice in the south. Dr Mott commented that a clear message was needed as to what should be first line and second line. **Agreed:** The views of the consultant urologists would be requested and the paper re-submitted to the December JAPC meeting.	**SD**
c.	**Aspirin and PPI** Mr Dhadli stated that it had been queried whether all patients on low dose aspirin should have proton-pump inhibitors (PPI) protection. A paper had therefore been produced which outlined the following:	

	• Evidence as to what constituted high risk. • The groups of patients who would benefit from PPI protection. • CKS non-steroidal anti-inflammatory (NSAID) prescribing issues. • A new US consensus document on the concomitant use of PPI which had been endorsed by the RDH consultant gastroenterologists. This recommended use of PPIs in patients at high risk of gastrointestinal (GI) bleeding but not in those at low risk. This included an algorithm for the PPI protection in patients on antiplatelet therapy. Mr Dhadli referred JAPC to the tabled PPI guidelines paper from Chesterfield Royal Hospital which indicated when a PPI should be used and highlighted some discrepancies between the two documents. One of these concerned the definition of older age as the CRH document indicated that this was >65 years and the consensus document >60 years. Mrs Needham added that it would be desirable to add the name of the recommended PPI and strength, lansoprazole 15mg to the document and clarity on when coprotection is required for patients. CRH have agreed to include an indication for the PPI on discharge in order to provide clarity for primary care and aid reviews. **Agreed:** JAPC agreed that a single document be produced based on the flowchart with the addition of the top and bottom sections of the CRH document, which outlined when PPIs were indicated together with the adverse effects and key points, and the reference to age amended to >65 years.	**SD** **SD**
7.	**SHARED CARE GUIDELINE**	
a.	**Riluzole** Mr Newman highlighted the amendments which had been made to the existing shared care guideline for riluzole for the treatment of the Amyotrophic Lateral Sclerosis (ALS) form of Motor Neurone Disease (MND). The main change concerned the monitoring requirements for liver function tests and FBC before and during therapy, every month for three months and then every three months for a further nine months and annually thereafter. **Agreed:** JAPC ratified the shared care guideline for riluzole for the treatment of the ALS form of MND.	**SD**
8.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations and drug discontinuations: Ondansetron orodispersible film – Tablets and injections currently brown so there was no requirement to add to the database or classify. Serevent Diskhaler – This had been now discontinued. Mr Dhadli would ascertain the extent of use from the prescribing data.	**SD**
9.	**MISCELLANEOUS**	
a.	**JAPC Updated Terms of Reference and Appeals** Mr Dhadli stated that following the last Derbyshire JAPC review the terms of reference had been updated to include an appeals process. Derbyshire JAPC would act as an independent body for appeals made against Nottingham's Area Prescribing Committee with regards to the process by which a decision was	

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

	made about a drug. There would be a reciprocal arrangement by which Nottingham Area Prescribing Committee would undertake a process review of the drug decisions made by Derbyshire JAPC. Mr Dhadli added that Ms Beverley Thompson and Mr Clive Newman had been included as deputies for DHcFT and RDH respectively. Mr Hulme commented that the CCG Chief Officers and Southern Derbyshire CCG Governing Body had requested clarification on point five in the rules of working section of the terms of reference and highlighted that the Chair should not be from a provider organisation. In connection with the reporting structure it was suggested that the wording should be amended to reflect that JAPC was accountable to the CCG Governing Bodies and its decisions need to be fed into the relevant CCG governance structure with escalation up to and including the Governing Bodies where appropriate. In addition it had been suggested that the names of clinicians should be taken out and replaced by roles and titles of people. **Agreed:** The terms of reference would be updated to reflect the comments made by the CCGs and the appendix changed with the addition of a separate list of membership with current incumbents.	**SD**
b.	**<u>Primary Care Management of Overactive Bladder (OAB)</u>** An updated guideline paper was tabled for discussion. Mr Dhadli highlighted the main changes made to the flowchart following the publication of NICE guidance CG 171 Urinary Incontinence: • Addition of propiverine 15mg into the medication box. • Update of new price change. • Addition of recommended six monthly review in the over 75 years of age. • Addition of a comment concerning the frail elderly and when to use a modified release preparation. • Addition of reference to the restriction of the number of OAB drugs tried before seeking alternative recommended treatments and consideration of referral to secondary care instead. Mr Dhadli reported that comments on the guidance had been received from Mr A Peracha, RDH Consultant Urologist, regarding tolterodine which was recommended as a second line treatment. Mr Peracha recommended that tolterodine be moved to first line treatment for the following reasons: • Much better tolerability. • Single daily dose. • Significantly reduced cholinergic side effects. • Minimal price difference when compared to oxybutynin 5mg BD. • Ease of management with two groups rather than three with no particular advantage and possible delay in symptomatic relief for the patients. Mr Peracha had also suggested that patients who did not respond or had poor tolerability should be referred to urology for consideration of intravesical botox or other treatment options.	

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

	During discussion Mr Dhadli advised that NICE had recommended oxybutynin or tolterodine or darifenacin as first line options based on the probability of it being cost effective under the NICE threshold of £20,000- £30,000 per QALY with oxybutynin and tolterodine having the highest probability of clinical effectiveness. Mr Hulme queried whether the third line options of propiverine, trospium, darifenacin, fesoterodine, mirabegron, solifenacin and duloxetine in the guidance were listed in terms of evidence. Mr Dhadli stated that the evidence for these was very limited and the drug of choice was based on cost effectiveness in terms of side effects. **Agreed:** JAPC ratified the OAB guidance with the agreed amendments.	**SD**
c.	**<u>Payment by Results (PBR) and Renavit</u>** Mr Dhadli advised that JAPC had decided at the October meeting to replace Dialyvit with the multivitamin Renavit. This had followed discussion on whether Renavit was included in tariff and it had been agreed to ascertain how the drug was funded and highlight that the decision to classify Renavit as a green specialist recommendation drug should not set a precedent for any future decisions. Mr Dhadli highlighted that JAPC should have understanding of payment by results and outlined the main points in the paper: • Cost of activity through a hospital fall under PBR. • PBR was a package of services which included drug costs. • Unless a drug was specifically listed as tariff excluded then by default it is within tariff when used as a part of a normal course of treatment. • High cost drugs excluded from tariff were split between NHS England and the CCGs. • Certain services were commissioned by NHS England and specialised services. • Not all activity was covered by national PBR.	
d.	**<u>Prescribing Specification</u>** Mr Dhadli stated that the prescribing specification held the prescribing element of the contractual agreement between the CCGs as commissioners and provider organisations. Discussion followed on the prescribing specification and some points were made: • Introduction - It was agreed that the list of documents should be removed and reference made only to the Outcomes Framework and NHS Constitution. • It was highlighted that the prescribing specification was a generic document which would go into every contract held by the CCGs. • The specification should be accepted in its current form in the knowledge that it would be applied to a number of Trusts and providers but the appendix should be taken out and a locally derived one developed in future to meet local need. • Section 2 - It was agreed to remove the whole section relating to new treatments and interventions. • Section 4 - It was agreed that the 100% compliance with the JAPC traffic light classifications be retained. • Section 6 - Shared care letter template – Dr Tooley highlighted the desirability of a more formal process for shared care agreements and that	**SD** **SD** **SD** **SD**

	these should be attached to the requests. Dr Game commented that the implementation of electronic letters made this a challenge for secondary care although the letters could contain links to the website which should be kept up to date. • Section 8 - Where a hospital clinician recommends that an out-patient goes to their GP for commencement of new treatment, five working days will be given for the GP to receive written information prior to the patient attending the practice. RDH had queried whether this was the Trust targets for sending information, GP target for reviewing and updating received information or the time patients need to allow for GPs to prescribe. It was agreed that clarification was needed and the discharge policy would be checked. • Section 9 - Health and social care staff should focus on medicines optimisation, supporting patients to get the best outcomes from their medicines, e.g. through better adherence, encouraging self-care and liaising with other providers (including community pharmacy) on discharge from hospital. It was agreed that this section be removed from section 9. • Section 11 – A comment had been made on the need to recognise the need for primary care representation at Trust Drugs and Therapeutic Committees. This had already been covered in section 1. • Mrs Needham highlighted an issue with the supply of NHS drugs on discharge to patients who had been in private hospitals. It was agreed that a line be added to indicate that this is in line with the discharge policy. • Section 18 - RDH had commented on the reference to the annual investment cycle. It was agreed that this should be included in the high cost treatment section of the specification. High Cost Drugs excluded from tariff commissioned by CCGs – Mr Dhadli outlined the amendments made to this section of the prescribing specification: • Addition of 'Excluded drugs and device costs charged to CCGS will be reflective of actual product cost to providers. CCGs reserve the right to audit provider costs to demonstrate compliance with this term.' • References to how patient level data would be audited. • Addition of 'Where agreement cannot be reached on share of gains, or proposals offer limited value, the provider will continue to pass through at cost to the CCGs' to section 14. • Amendment to section 17 to read 'Excluded drugs/devices recommended within a NICE Interventional Procedures Guidance (IPG) and/or guideline will not be routinely funded unless endorsed within a national or locally agreed clinical commissioning policy.' • Amendment to section 18 to read 'Budgets for excluded drugs and devices will be set on an annual basis. This will be based on the provider's assessment of need through horizon scanning, and agreed through a confirm and challenge meeting by the host commissioning CCG with the provider.' During discussion Mr Dhadli referred to the NHS England document 'Prescribed Specialised Commissioning Intentions' and advised that some aspects from this had been included in the specification. Mr Newman	**LH** **SD** **SD** **SD**

	expressed some concern that the context of working to establish national frameworks and payment arrangements had not been adequately reflected in the specification and was currently being developed. Mr Newman added that RDH was unable to provide some requirements of the specification in terms of patient level data and information sharing. Mr Dhadli commented that it was intended to obtain assurance as to whether drugs were being used appropriately according to NICE guidance and that the specification was used to ensure that progress was made in this area. Dr Henn suggested that a qualifying statement could be inserted to indicate that information sharing was in line with information governance and that this would cover this area. Dr Henn highlighted an issue of quality and safety concerning out-patient pharmacy services which was not included in the prescribing specification. A number of patients had reported that they had not been informed that they should have received an out-patient prescription from the hospital out-patient pharmacy and also that waiting times were in the region of 90 minutes to two hours. This had led to patients leaving hospital without prescriptions and consequently presenting to primary care with inadequate prescriptions leading to concerns about safety, quality and duplication of resources. Dr Shearer added that Healthwatch Derbyshire had received comments from patients that the waits varied between twenty minutes and two hours. Mr Newman stated that the outpatient pharmacy waits were an average of twenty minutes and the situation was monitored very closely via key performance indicators. Dr Tooley commented that there may be an issue due to inaccurate reporting from some patients and Mrs Hunter queried whether this could be picked up by quality leads and included in quality targets. Mr Shepherd highlighted that there was a risk that the prescribing specification could become a commissioning specification for hospital pharmacy services and that this be addressed by another forum. Mr Shepherd added that it would be helpful to receive details of problems which arose rather than relying on anecdotal evidence which made it much more difficult to resolve. Mr Hulme suggested that appendix one be taken out and replaced by a generic medicines optimisation document. It was agreed that a reference to the national indicators would be included.	**SD** **SD**
e.	**<u>Midlands Therapeutic Review and Advisory Committee (MTRAC) Reviews</u>** The MTRAC Commissioning Support Reviews on dapagliflozin for the treatment of type 2 diabetes and insulin degludec for the treatment of diabetes were noted by JAPC.	
10.	**JAPC BULLETIN**	
	Mr Dhadli highlighted that the gender services update had been amended in order to clarify what should be done about existing patients. The amended JAPC bulletin was ratified by JAPC.	
11.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Update for October 2013 was noted. Mr Dhadli highlighted the following:	

	• The clarified contraindications of risk of serious haemorrhage now applied to all three new oral anticoagulants (apixaban, dabigatran and rivaroxaban) for all indications and doses. The local guidance, formulary chapter and AF guidance had been consequently updated. • The Yellow Card Scheme had been updated to enable patients for the first time to see the black triangle (▼) in the Patient Information Leaflet for relevant medicines. The leaflet would explain that the miedicine was subject to additional monitoring to allow quick identification of new safety information and that patients would be able to report suspected adverse reactions on a Yellow Card.	
12.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in October: TA 297 Ocriplasmin for treating vitreomacular traction. Mrs Qureshi would circulate the costings for this drug to the CCGs. Ocriplasmin classified as a **RED** drug.	**SQ** **SD**
13.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Raloxifene – GREEN 2nd line consultant initiation for familial breast cancer. Propiverine – GREEN 3rd line after trial of oxybutynin and tolterodine. Duloxetine – GREEN 2nd line after trial of oxybutynin and tolterodine and if surgery not suitable. Ocriplasmin – RED as per NICE TA 297	
15.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Shared Care Disulfiram – This was included in the DHcFT workplan. Transgender Prescribing – Awaiting national guidance at the end of 2013. Actinic Keratosis – A draft formulary and advice was being developed by RDH and CRH consultant dermatologists. Rivaroxaban – The development of a DVT pathway had been delayed by the absence of the member of staff. Rifaxamin for HE – NICE guidance was expected in January 2014. Diabetes Guidelines – This was being drafted by a F2 doctor. Lisdexamfetamine – The update of the shared care was on the workplan. Lixisenatide – Review of efficacy of GLP1 (wt and HB1Ac) use against NICE audit criteria due in October 2014.	
16.	**GUIDELINE GROUP ACTION TRACKER**	
	The Guideline Group action tracker was ratified by JAPC.	

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

17.	**MINUTES OF OTHER PRESCRIBING GROUPSP**	
	• Chesterfield Royal Hospital Drugs and Therapeutic Committee – 17 September 2013 • Derbyshire Community Health Services MOST – 11 September 2013 • Sheffield Area Prescribing Group – 16 July 2013 • Sheffield Area Prescribing Group – 17 September 2013 • STAMP – 10 September 2013	
18.	**ANY OTHER BUSINESS**	
a.	**Dapagliflozin** Dr Game advised that JAPC had previously classified dapagliflozin as specialist initiation but as the prescribing would be actioned via GPs this should be changed to specialist recommendation. **Agreed:** Dapagliflozin proposed to be re-classified from BROWN specialist initiation to Brown after specialist recommendation. Post meeting note- this decision was retracted following Decembers JAPC meeting as not a valid reason for re-classification. Dapagliflozin remains Brown after specialist initiation	**SD** **SD**
b.	**Future of JAPC** The future chairing, administration and venue for JAPC would be determined outside the meeting.	**JB/SD**
c.	**Molludab (5% Potassium Hydroxide Solution)** Mrs Needham reported that the use of molludab for the treatment of molluscum contagiosum had been discussed by the North prescribing sub-group and the GPs on the sub-group had expressed the view that it did not need to be specialist prescribed and primary care should not have to refer to a specialist or dermatology champion to access treatment. The GPs felt that it should be only for exceptional use and highlighted that no treatment is the first-line option. It had been recommended by the group that JAPC assign a traffic light classification of brown for use in exceptional circumstances only to avoid it being prescribed a lot. Dr Tooley and Dr Emslie highlighted that it was important to convey the message that Molludab was only for very exceptional circumstances. Dr Shearer commented that there was a potential for increasing demand by patients for this drug. **Agreed:** It was agreed to leave the classification of Molludab as a red drug for specialists and GPs specially trained in dermatology and dermatology champions. This decision would be reviewed in six months in the light of what happened with referrals.	
d.	**Guidelines Group Terms of Reference** Mr Dhadli advised that Mrs Qureshi (NICE audit pharmacist) and Ms Pardeep Chera (integrated pharmacy technician) would be added to the membership of the Guidelines Group.	**SD**
e.	**Indapamide in Hypertension** A paper on the use of indapamide in essential hypertension would be brought to	

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

	the next JAPC meeting.	
19.	**DATE OF NEXT MEETING**	
	Tuesday, 10 December 2013 in the Post Mill Centre, South Normanton.	