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

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 14 May 2013

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Abatacept	RED as per NICE TA 280
Canakinumab	BLACK- NICE TA 281
Pirfenidone	RED - NICE TA 282
Rosuvastatin	BROWN following specialist recommendation
Linaclotide	BLACK

Clinical Guidelines

Identification and management of familial hypercholesterolaemia
Appropriate lipid modification therapy in non-familial hyperlipidaemia

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

Present:	
Derbyshire County Council	
Dr J Bell	Assistant Director of Public Health (Chair)
Mrs S Qureshi	NICE Liaison and Audit Pharmacist
Southern Derbyshire CCG	
Mr S Hulme	Head of Prescribing
Mrs L Hunter	Assistant Chief Finance Officer
Dr A Mott	GP
Dr I Tooley	GP
North Derbyshire CCG	
Dr C Emslie	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 D McLean	Principal Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Mr D Branford	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
In Attendance:	
Mr A Thorpe	Derby City Council Public Health (minutes)

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

Item		Action
1.	**APOLOGIES**	
	Dr Fitzsimons and Mr M Steward.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Patient Group Directions (PGDs) • New drug assessment - Linaclotide	
4.	**MINUTES OF JAPC MEETING HELD ON 9 APRIL 2013**	
	The minutes of the meeting held on 9 April 2013 were agreed as a correct record with the following amendments: Attendance: Amend to: Dr I Tooley and Mrs Needham to represent North Derbyshire CCG and Hardwick CCG. Shared Care Pathology Group – Add 'The Group did not deal with guidelines which involved drugs'. Mirabegron – Amend to 'Participants were recruited aged 18 and over with symptoms of OAB for three or more months and were excluded from the study if they showed significant stress incontinence or stress predominant mixed incontinence at screening, or an average total daily urine volume > 3000mls during run in assessment.' Clinical Guidelines – Amend to 'Clarity was also needed for primary and secondary failure and audit results would be advantageous.' Glaucoma Preservative Free Eye Drops – Amend to 'Mr Dhadli to amend the glaucoma guidelines to reflect the change in the pathway.'	
5.	**MATTERS ARISING**	
a.	**Glaucoma Guideline** It was reported that the guideline had been amended.	
b.	**Clinical Guidelines** Mrs Qureshi had met with Dr Rabindranathnambi to discuss psoriasis and the guidelines would be presented to the Clinical Commissioning Policy Group next week. Antimicrobial treatment guideline -The amended guidance would be brought back for discussion at the June JAPC meeting by Dr Diane Harris.	**SD**
6.	**LIPID AND FAMILIAL HYPERCHOLESTEROLAEMIA (FH) POLICIES**	
a.	Dr Bell stated that a working group which had included primary care commissioners, secondary care consultants from Acute Trusts, GPs and lead pharmacists had met to update the FH policy and secondary prevention policy in line with national guidance and TAs.	

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

Item		Action
	Mr Dhadli referred JAPC to the FH policy which had been updated to include rosuvastatin as a treatment option in the event of complete intolerance of simvastatin, atorvastatin and pravastatin or partial tolerance of other statins at low moderate doses. In addition ezetimibe as monotherapy treatment option and in combination. Dr Roger Stanworth, RDH Consultant Cardiologist, had subsequently made some further amendments to the FH policy: • Patients not able to tolerate one statin may benefit from a trial with another. Simvastatin 40mg is first line followed by atorvastatin 10mg and then pravastatin 10mg. It was agreed that the reference to pravastatin be further amended to reflect low dose in cases of patient intolerance and titrate up to therapeutic dose of 40mg. • Ezetimibe in combination with a statin is an option only if recommended by a lipidologist. Dr Stanworth asked for the reference to lipidologist be removed. • A recent article in the British Medical Journal had recommended U&E monitoring in additions to and LFT monitoring for simvastatin 40mg or more, atorvastatin 20mg or more and rosuvastatin. Mr Dhadli added that the SPCs did not reflect to this monitoring for any of these drugs with the exception of rosuvastatin and that the monitoring should remain as currently indicated. Dr Mott queried whether all patients with FH should be referred for confirmation and genetic testing and, if so, that this should be included in the bullet points at the front of the document. Clarity was required as to whether all patients should be referred particularly if they were already part of a family with FH and they responded well to their statins. However in a new case where a family had not been diagnosed with FH they would need to be referred and NICE had indicated that patients should be offered a referral. Discussion followed on the policy for appropriate lipid modification therapy in non-familial primary hyperlipidaemia. Mr Dhadli reported that the old policy had been revised and changes made to reflect NICE TA adherence and the lack of clarity about the use of ezetimibe either in combination or use in monotherapy. For primary prevention the 'fire and forget' policy remained unchanged but for secondary prevention the guidance now included atorvastatin and allowed for intensification of treatment in high risk patients as defined in the cover sheet. Ezetimibe could be used as defined by the then NPC which had summarised the NICE TA recommendations in order to remove any ambiguities as to its use. Dr Stanworth and the working group had subsequently made some amendments to the policy: • Use of lower doses for intolerance and titrate up to therapeutic dose as the best way of dealing with compliance issues. • Ensure that it is clear in all relevant points of the document that primary prevention did not apply to certain groups such as patients with diabetes. It was agreed that this section should read 'Intensification of treatment is not recommended in primary prevention.' • The section which referred to patients with Acute Coronary Syndrome (ACS) had been changed by the Working Group to 'Patients with ACS may benefit	**SD** **SD** **SD**

Item		Action
	from a high intensity statin (atorvastatin 80mg) on the advice of a consultant cardiologist. Lower doses were appropriate if patients were unable to tolerate. A 12 month review should take place with a view to reduce the dose.' Mrs Needham commented that the working group had recommended that the dose should be reduced or an alternative statin prescribed if the patient did not tolerate the highest dose of atorvastatin 80mg. It had been highlighted that the flexibility that it would not automatically be atorvastatin 80mg in ACS and may be individualised after review of a patients' co-morbidities. Dr Tooley highlighted the need for guidance as to what should be included in a 12 month review. It was agreed that this section should refer to the need for a review at 12 months with a view to a reduction in the dose and not necessarily by a cardiologist • Dr Baron had commented on the use of bold type to highlight the use of ezetimibe and its place as an option for combination therapy with a statin only following lipidologist recommendation. Mr Hulme commented on the need to highlight that not prescribing was an option and that the policy applied to new patients and existing patients should be reviewed at an appropriate time in the light of this guidance. The reasons for the change in policy concerning the use of ezetimibe and its inclusion in the guideline should be made clear. Dr Bell stated that ezetimibe was the subject of a NICE TA and had therefore been included in the algorithm within the guideline but its use was not promoted any further than previously had been the case. Dr Game referred to the comment made by Dr Stanworth concerning the lack of capacity in the lipid clinic to see patients with diabetes being considered for ezetimibe. It was therefore agreed that the reference to lipidologist recommendation should be removed. Mrs Needham also referred to the requirement for GP practices to commence cholesterol testing to achieve payments under QoF because the statin local arrangement will no longer be in place and raised the need for this to be carefully communicated to primary care. **Action:** Mr Dhadli would incorporate the amendments suggested by Dr Stanworth in the guidance and change the algorithm to reflect the discussions by JAPC. **Action:** A reference to the use of ezetimibe and GP practice cholesterol testing would be included in the JAPC bulletin. Mr Hulme would supply the wording concerning ezetimibe to Mr Dhadli. **Action:** Mr Dhadli would contact Dr Stanworth to request criteria for referral for the identification and management of familial hypercholesterolaemia policy **Agreed:** Rosuvastatin re-classified as a **BROWN** specialist recommendation drug. **Agreed:** JAPC ratified the policy for appropriate lipid modification therapy in non-familial hyperlipidaemia and familial hypercholesterolaemia guidance	**SD** **SD/SH** **SD** **SD** **SD**
7.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches and new drug formulations: New Drug Launches:	

Item		Action
	• Linaclotide – To be reviewed • Lisdexamfetamine dimesylate –To be placed on the unclassified database to either wait for NICE guidance or for DHcFT to put forward a proposal for its use. New Drug Formulations: • Medroxyprogesterone acetate injection – To be reviewed by JAPC in June.	
8.	**JAPC BULLETIN**	
	The following changes to the JAPC bulletin were noted: C.difficile - Change to read Clostridium difficile. Mirabegron – Addition of additional sentence to read 'Classified as red while awaiting NICE guidance. Ingenol – Remove word 'upon'. The amended JAPC bulletin was ratified by JAPC.	
9.	**MHRA DRUGS SAFETY UPDATE**	
	The MHRA Drug Safety Alert for April 2013 was noted. Mr Dhadli highlighted the following MHRA advice: The basal insulin analogue insulin degludec was available in prefilled pen devices in two strengths: 100units/mL and 200 units/mL. Insulin degludec was not currently on the formulary but the potential for incorrect dosing needed to be highlighted in the update of the diabetes guideline. Dr Game commented that insulin degludec only came in a prefilled pen which dialled up in units and this would not be a big risk in terms of dosing. There would be occasional patients for whom the use of insulin degludec would be beneficial but this would be considered by RDH Drugs and Therapeutic Committee and working group. Mr Dhadli also noted a recent MTRAC review February 2013 indicating a "lower place" in therapy and its "weaker evidence" strength Cilostazol locally classified as black. JAPC noted the risk of cardiovascular and bleeding events Healthcare professionals were requested to be vigilant over recent drug name confusion. This had been included in the monthly newsletter. A risk of serious cardiac disorders for patients on strontium ranelate and consequent restricted indications, new contraindications and warnings. These patients would need to be reviewed and this would be highlighted in the bulletin.	
10.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance: TA 278 Omalizumab for treating severe persistent allergic asthma – This guidance replaced TA 133 and TA 201. Omalizumab had already been classified as a RED drug.	

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

Item		Action
	TA 279 Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures – This was received for information. TA 280 Abatacept for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs – This guidance replaced TA 234. Abatacept classified as a **RED** drug. TA 281 Canakinumab for treating gouty arthritis attacks and reducing the frequency of subsequent attacks – This was a terminated appraisal. Canakinumab classified as a **BLACK** drug. TA 282 Pirfenidone for treating idiopathic pulmonary fibrosis – There were costing implications for NHS England and strict criteria for the patient access scheme. It would therefore be necessary for providers to maintain accurate data. Pirfenidone classified as a **RED** drug.	**SD** **SD** **SD**
12.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Abatacept – RED Canakinumab – BLACK Pirfenidone – RED Rosuvastatin – BROWN following specialist recommendation Linaclotide- BLACK	
13.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: PGDs – To be brought back to the June JAPC meeting. Shared Care Disulfiram – To be brought back to the JUNE JAPC meeting. ECG monitoring – To be followed up by Dr Bell. Fluorouracil 5% - Mr McLean advised that the East Midlands Cancer Network had been dissolved and therefore there was no current forum where this could be discussed. The NHS England Area Teams had appointed specialist cancer pharmacists who would be able to advise in future. Dr Mott commented that the dermatologists in the north were happy to use this drug but the Derby dermatologists were not. The challenge concerned the diagnosis and there was a lack of consistency about the use of the three dermatology drugs including 5 FU. It was agreed that the three drugs together and the cost effectiveness and training implications discussed at the June JAPC meeting. Seretide - To be brought back to the July JAPC meeting. Rufinamide – To be brought back to the June JAPC meeting.	**SD/SH** **SD** **JB** **SD** **SQ** **SD/SH**

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

Item		Action
	Diabetes Guidelines – To be brought back to the August JAPC meeting. Fosfomycin – An implementation plan had been sent to Southern Derbyshire CCG and fosfomycin would consequently be removed from the list.	**SD/FG** **SD**
14.	**GUIDELINE GROUP**	
	The Guideline Group action tracker was ratified by the JAPC.	
15.	**MINUTES OF OTHER PRESCRIBING GROUPS FOR INFORMATION**	
	• Burton Hospitals Drugs and Therapeutic Committee 18/3/13 Mr Dhadli highlighted the discussion about dabigatran at this meeting concerning a patient who had had a stroke after missing three days of medication.	
16.	**ANY OTHER BUSINESS**	
a.	**PGDs** Mr Hulme would check whether these could be presented to the June JAPC meeting.	**SH**
b.	**New Drug Assessment - Linaclotide** Mr Dhadli advised that linaclotide was a novel guanylate cyclase-C agonist (GCCA) drug licensed for symptomatic treatment of moderate to severe irritable bowel syndrome (IBS) with constipation in adults. The evidence summary for JAPC came from NICE and RDTC reviews from two phase 3 double blind placebo controlled RCTs of patients with IBS with constipation. Both studies had demonstrated that patients on linaclotide versus placebo met the FDA and EMA efficacy endpoints. Safety had also been assessed over twelve weeks in trial 1 and over 26 weeks in trial 2. The EMA were awaiting long term safety data and there was some post authorisation safety data requested to investigate the complications of diarrhoea which was the most common side effect. Mr Dhadli gave background to the NICE treatment of IBS and presented costs of conventional treatments. Mr Dhadli then went on to list the study limitations which included no head to head studies with an active comparator and concerns over long term effects with increased electrolyte secretions. IBS was estimated to affect between 10 to 20% of the general population and about a third with IBS. **Agreed:** Linaclotide classified as a **BLACK** drug.	**SD**
17.	**DATE OF NEXT MEETING**	
	Tuesday, 11 June 2013 in the Post Mill Centre, South Normanton.	