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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 14 October 2014

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Umeclidinium/Vilanterol (Anoro)	BLACK
Lurasidone	RED
Lenalidomide	RED as per NICE TA 322

Clinical Guidelines

Rheumatoid Arthritis Commissioning Algorithm for Specialised Drugs

Patient Group Directions (agreed for NHSE use)

DTaPIPVHiB Pediacel or Infanrix IPV HIB
Fluenz tetra nasal
Meningococcal A,C,W and 135 Conjugate Vaccine
Pneumococcal Conjugate Vaccine PCV

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
Dr C Emslie	GP
Dr D Fitzsimons	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Erewash CCG	
Dr M Henn	GP
Derbyshire County Council	
Derby Hospitals NHS Foundation Trust	
Dr W Goddard	Chair- Drugs and Therapeutic Committee
Derbyshire Healthcare NHS Foundation Trust	
Dr S Taylor	Chair – Drugs and Therapeutic Committee
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Ms S Basi, Dr R Dewis, Mr C Newman, Dr T Parkin and Mr M Steward (and deputy). It was noted that there was no representation from Derbyshire Community Health Services NHS Trust. The quoracy of the JAPC meeting had been addressed by exceptional allowance when the Trust had been requested to comment on the agenda papers in advance.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	No declarations of any other business were made.	
4.	**MINUTES OF JAPC MEETING HELD ON 9 SEPTEMBER 2014**	
	The minutes of the meeting held on 9th September 2014 were agreed as a correct record after the following amendment: Summary Points - Amend to: All formulations of alprostadil - BROWN after specialist initiation as per SLS criteria; usually 2nd line to a PDE- 5 inhibitor. Fluticasone propionate nasal drops – Amend to: GREEN consultant/specialist initiation for the management of chronic rhinosinusitis with nasal polyps. Antimicrobial Treatment Guidelines/Antimicrobial Guidance for the Management of Lower UTI in Chronic Kidney Disease (CKD) – Antimicrobial Treatment Guidelines/Antimicrobial Guidance for the Management of Lower UTI in Chronic Kidney Disease (CKD) – Amend to ' Mr Hulme reported that RDH would be releasing the sensitivity testing for pivmecillinam for lower UTIs and CRH currently would only test sensitivity to pivmecillinam if samples are resistant to trimethoprim, nitrofurantoin and amoxicillin. When the new equipment has been bought sensitivity to pivmecillinam will be done routinely on all urine samples at CRH. NICE Summary – Amend to: Dr Mott had understood from the hospital that it could be used but this was not recommended by either the renal team or laboratory. Indapamide – Amend to: Indapamide 2.5mg immediate release had been classified as green in 2011 and the modified release (MR) formulation had been classified as brown in 2013 based on cost. Agreed: Bendroflumethiazide would remain first line choice diuretic and the thiazide-like diuretics, including indapamide 2.5mg and indapamide MR. would be 2nd line and choice should be based on the lowest acquisition cost. Ondansetron – Amend to: It was therefore decided to seek a traffic light classification for ondansetron for this indication as this was referred to in the national guidance for the treatment of HG. All other options for treatment of HG were also unlicensed for use in pregnancy and the evidence suggested that ondansetron was considered safe. Ondansetron is classified already as	

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	a BROWN drug for the licensed indications for palliative care and chemotherapy.	
5.	**MATTERS ARISING**	
a.	**Vigabatrin** Dr Goddard reported that Dr Will Carroll, Consultant Paediatrician, would develop a pathway.	
b.	**Atrial Fibrillation (AF)** Mr Dhadli referred to a request from some of the consultant cardiologists for the use of NOACs to facilitate timely DC cardioversion. This had been excluded from the AF guidance. Mr Dhadli evidenced the lack of robust evidence supporting this by summarising the key points from a European Society of Cardiology publication. Dr Goddard would check with Dr Julia Baron.	**WG**
6.	**NEW DRUG ASSESSMENTS**	
	Umeclidinium/Vilanterol (Anoro) Mr Dhadli reported that umeclidinium/vilanterol was a licensed combination inhaler used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). This was the second LAMA/LABA combination to be launched as the first one had been Ultibro (indacaterol and glycopyrronium inhaler). There had been a SMC review on the licensed dose and the use of umeclidinium/vilanterol had been rejected. The evidence came from four phase 3 RDBCT studies, three active controlled and one placebo controlled trials. All the studies had a tiotropium 10mcg arm and umeclidinium/vilanterol 55/22 mcg group plus arms of added variation double strength umeclidinium/vilanterol and monotherapy arms. Mr Dhadli highlighted the results of the studies: • For disease orientated outcomes there was a statistically significant improvement in primary and secondary outcomes of Fev1 versus tiotropium. However they were not all clinically significant nor was this against an appropriate active comparator (LABA+LAMA versus LAMA). • Significantly greater reduction in rescue medication measured by use of salbutamol on only two of the studies. • Breathlessness measured using the Transition Dyspnoea Index. There had been no difference in two of the studies and the third did not measure. • SGRQ used for QoL measure. No significant difference in two of the studies and third statistically significant but not clinically significant. • The studies had been for LABA + LAMA versus LAMA. The EMA classified lung function as a surrogate marker with a need to include a co-primary endpoint that is a symptom based endpoint or a patient related endpoint; neither of which were included in the primary outcomes. Mr Dhadli added that there was long term safety data and some concern about cardiac affect and arrhythmias. **Agreed:** Umeclidinium/Vilanterol (Anoro) classified as a **BLACK** drug.	**SD**

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7.	**CLINICAL GUIDELINES**	
a.	**Rheumatoid Arthritis Commissioning Algorithm** Mrs Qureshi reported that variations had been agreed with RDH to the commissioning algorithm for rheumatoid arthritis published by NICE. JAPC was requested to agree that these could be implemented Derbyshire-wide. The recently agreed and past variations were summarised: • Biologic withdrawn at any time if the patient developed an adverse reaction to the drug (instead of within the first six months of treatment). • Rituximab would be given as monotherapy if patient was contraindicated or not able to tolerate methotrexate. • Tocilizumab and abatacept would be given as a subcutaneous injection rather than an IV infusion. • Tocilizumab monotherapy (without MTX). Mrs Qureshi added that RDH had indicated that there were three existing IV patients who they wanted to give tocilizumab as a subcutaneous injection at an estimated additional cost of £10,000 each. Mr Hulme queried whether these were existing or new patients - Mrs Qureshi would check on this. Mr Dhadli highlighted that an addition should be made to the commissioning algorithm to indicate that toclizumab subcutaneous injection would only continue to be commissioned with the proviso that the patient access scheme was still available. **Agreed:** JAPC ratified the revised Derbyshire-wide rheumatoid commissioning algorithm with the agreed addition.	**SQ** **SD**
8.	**PATIENT GROUP DIRECTIONS (PGDs)**	
a.	**DTaPIPVHiB Pediacel or Infanrix IPV HIB, Fluenz Tetra, Meningitis ACWY, Pneumococcal Conjugate Vaccine PCV** JAPC noted the PGDs for DTaPIPHIB Pediacel or Infanrix IPV HIB, Fluenz Tetra, Meningitis ACWY and Pneunococcal Vaccine PVC. **Action:** These will be added and uploaded to the website.	**SD**
9.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations and drug discontinuations: Launches in the UK: Empagliflozin (Jardiance) – NICE TA expected in December 2014. Lurasidone (Latuda) – Classified as RED and to be discussed by the DHcFT Drugs and Therapeutic Committee. Licence extensions: (for information and consideration) Aflibercept (Eylea) Bevacizumab (Avastin) Etanercept (Enbrel) Ivacaftor (Kalydeco)	

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	Obinutuzumab (Gazyvaro) Regorafenib (Stivarga) Drug discontinuations in September: Ecostatin (econazole) Fluarix (influenza vaccine) – to be replaced with Fluarix tetra. Fluenz (influenza vaccine – to be replaced with Fluenz tetra. Fluvirin (influenza vaccine) – to be replaced with Fluvirin tetra. MaxEPA (eicosapentaenoic acid/docosahexaenoic acid) Miniversol (sodium chloride) Miniversol Water Tonpular XL (venlafaxine)	
11.	**MISCELLANEOUS**	
a.	**Insujet** Mr Dhadli reported that JAPC had classified Insujet, a needle-free insulin device, as a BLACK drug in April 2012. JAPC, at the request of the Complex Case Panel, had been requested to re-visit this decision following an Individual Funding Request (IFR) of a needle phobic patient. Mr Dhadli added that JAPC did not normally re-consider previous decisions unless there was significant new evidence or all significant evidence had not been considered at the time of the decision. Neither of these criteria was met. The current process for clinicians requesting a BLACK drug is the IFR request route. Mr Dhadli explained that the CCG has an IFR Panel which had been established with very robust structures to consider requests that support with the NHS Constitution around decision making. Patients to be eligible would either be rare, meeting certain criteria of incidence and prevalence, or exceptional. In addition there was a Complex Case Panel which considered patients in complex circumstances. During discussion Mr Hulme stated that there was a lack of a mechanism to agree Black drugs for individual patients with the IFR process being the only mechanism. With the case in question the IFR Panel screened out the request and it had been subsequently debated at the Complex Case Panel. Mrs Needham referred to the broader question of the management of Black drugs which were not as clearly defined in terms of exceptionality and queried whether public health would be able to develop a policy. Dr Mott commented that Insujet could either be left as Black or re-classified as Brown for patients with a confirmed psychological phobia. Mr Hulme advised that the Complex Case Panel terms of reference were being reviewed in order to make them more clearly defined. This process was being led by Dr Robyn Dewis, Derby City Consultant in Public Health Medicine, and Eleanor Rutter, Derbyshire County Consultant in Public Health. Mr Dhadli added that the commissioners could request that this panel consider Black drugs as well as complex cases. **Action:** Mr Dhadli would draft a letter on behalf of Dr Mott to request that public health develop a process around Black drugs.	**SD**

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	Action: A list of the drugs which had previously been classified as black by JAPC would be reviewed at the November meeting.	**SD**
b.	**<u>Prescribing Specification</u>** Mr Dhadli advised JAPC that the Derbyshire Prescribing Specification contained the prescribing element of the contractual agreement between CCGs as commissioners and the provider organisations. Mr Dhadli highlighted the following proposed changes: • Amend to - Drugs and treatments commissioned by NHS England are not included into this prescribing specification. • Amend to - The requirements set out in this prescribing specification applies to private providers of healthcare where patients treated privately transfer into the NHS. Patients moving into an NHS setting will be treated the same way as any other NHS patient and GPs will prescribe in line with local policies. Private patients prescribed non-Derbyshire formulary items will be counselled to expect NHS Derbyshire formulary drugs if moving into the NHS. Mrs Needham commented that it should be emphasised in the prescribing specification that patients who were referred under the NHS to private providers were also included. Mr Dhadli would add this to the specification. • Section 4 – Amend to 'adhere to the definition of initiation and recommendation.' Mrs Needham advised that the reference to drugs in the section for each of the colour classifications should also include 'devices'. Mr Dhadli would amend this section. • Section 5 - The Derbyshire Local Medical Committee had suggested that the following amendment should be included 'For all drugs started in a provider care setting the initiating clinician is responsible for the following: considering and advising on contraindications, side effects and interactions, patient counselling, baseline investigations, where appropriate the provision of management plans when starting new medicines and on-going monitoring e.g. blood test or ECGs until agreed and accepted by the patient's primary care clinician'. Following discussion it was agreed that this section should be amended as follows: 'For all drugs started in a provider care setting the initiating clinician is responsible for .....and for informing the primary care physician as to the safety of the on-going monitoring'. • Section 10 – JAPC members commented that the statement was difficult to understand with references to both fourteen days and twenty-eight days supply. In order to simplify it was agreed to change to the need to ensure at least fourteen days supply of all medicines on discharge or transfer. It was noted that RDH had proposed a further change in recognition of the short stay and FEAT (Frail Elderly Assessment Team) work to improve fast discharge. Mr Newman was not present at JAPC and he would be asked to present this case at next month's meeting. • Section 24 – Amend to 'Medication required for planned hospital procedures (for example, EMLA® cream before hospital dialysis) medication will be prescribed by the treating clinician'. • High Cost Drugs excluded from Tariff commissioned by CCGs –	**SD** **SD** **SD** **SD**

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	Amend to 'Providers should have in place systems to ensure that medicines excluded from tariff are only charged to the CCG for those uses the CCG have agreed to commission. This includes where there are dual or multiple uses for medicines.' • Appendix 1 QIPP – The QIPP indicators would be retained. • Appendix 2 - The CCGs of Derbyshire and JAPC support the medicines optimisation through collaborative working with our provider organisations. Mr Newman had suggested that some Medicines Optimisation specific outputs be included. It was agreed that possible inclusions be agreed between representatives from North and South Derbyshire and agreed at the next JAPC meeting.	**KN/SH/CN**
	Dr Henn stated that access of patients to medications had been omitted from the specification including timely access for patients to out-patient prescriptions. Dr Henn also highlighted a gap in provision due to the lack of an out-patient pharmacy at London Road Community Hospital in Derby and that patients had to obtain these at the main hospital site or arrangements made to deliver the medicines to a branch of Boots nearest the patient's home. Dr Mott and Mr Hulme would raise this issue at their next meeting with Mr Newman.	**SH/AM**
	Agreed: JAPC ratified the prescribing specification with the agreed amendments.	**SD**
c.	**<u>Sulfasalazine Monitoring</u>** Dr Fitzsimons stated that JAPC had recently updated its shared care for sulfasalazine following a SPC change. However this had caused some confusion as patients who were still under secondary care for their sulfasalazine were being told by their consultants that they did not require monitoring in the long term every three months. This was a major change for those patients who had not been monitored following two years of treatment but were now required to have three monthly blood tests. Dr Fitzsimons highlighted that there was a lack of monitoring for drugs of the same class: mesalazine, balsalazide and olsalazine. Dr Fitzsimons also highlighted the need for clarification as to whether monitoring was required for all these drugs.	
	During discussion Dr Goddard commented that the gastro-enterologists had looked at the evidence for increased monitoring but there had been no consensus of opinion. Dr Mott highlighted that it would be necessary to be very clear as to the reason for any deviation from the SPC. Mrs Needham confirmed that there was some monitoring in the SPC for mesalazine, balsalazide and olsalazine and shared care was not required. Clarity was needed to raise awareness of the need to supply advice and information from secondary care to primary care concerning the on-going monitoring and for education for patients who could experience changes to their monitoring.	**KN/SD**
	It was agreed that the shared care of sulfasalazine should include the monitoring requirements within the updated SPC. Dr Goddard and Mr Shepherd would convey the message about increased monitoring to their	**WG/MS**

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	respective Drugs and Therapeutic Committees, and on to their consultants. Mr Dhadli to include monitoring advice of mesalazine, balsalazide and olsalazine into the formulary.	**SD**
	Agreed: It was agreed to adhere to the SPC monitoring for sulfasalazine and to update the BNF chapters with monitoring requirements for mesalazine, balsalazide and olsalazine.	**SD**
d.	**<u>Chronic Obstructive Pulmonary Disease</u>** Mr Dhadli reported that NICE had published an evidence summary in September 2014 for Fostair, a combination inhaler containing beclometasone and formoterol, for its new licenced use in COPD. The evidence was based on two RCTs, one of which compared Fostair with Symbicort and the other with Seretide. The trials revealed that Fostair was non-inferior and cheaper. Mr Dhadli also referred to an updated Cochrane review of tiotropium which had good patient-orientated outcomes and reduced exacerbations requiring hospitalisation. The purpose of the Fostair paper was to give assurance to JAPC members that a previous decision to use Fostair off label for COPD was justifiable. The tiotropium Cochrane review added to the evidence and why JAPC should continue to recommend tiotropium as a preferred LAMA.	
e.	**<u>Debrisoft</u>** Mr Dhadli reported that feedback had been received from practice pharmacists to request that the current classification of Debrisoft by JAPC as RED should be re-visited with concerns over access to the dressings. It had been highlighted that the Tissue Viability nurses advised practice nurses and district nurses to use Debrisoft but they were not clinically responsible for patient care as the practice or district nurse administered and supplied dressings to the patient. Mr Hulme requested more information from the tissue viability service and the rationale for the original decision of RED. **Agreed:** Debrisoft to remain classified as a **RED** drug and more information on its use to be obtained for further discussion by JAPC.	**SD**
12.	**JAPC BULLETIN**	
	Dr Mott pointed out that the section on alprostadil topical cream should read 'Alprostadil topical cream is a synthetic vasodilator used in the treatment of erectile dysfunction. Similar to intracavernosal formulations administration requires patient training.'' Mr Dhadli would amend accordingly.	**SD**
	The amended JAPC bulletin was ratified and ready for circulation.	**SD**
13.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Update for September 2014 was noted. Mr Dhadli highlighted the following: • Denosumab – minimisation of the risk of osteonecrosis of the jaw and monitoring for hypocalcaemia—updated recommendations. Mr Dhadli advised that the current shared care had been updated and sent to one of the nurses for agreement. The amended shared care would be	**SD**

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	brought to a JAPC meeting. • Nitrofurantoin for urinary-tract infections was now contraindicated in most patients with an estimated glomerular filtration rate (eGFR) of less than 45 ml/min and lower in certain circumstances. Mr Dhadli highlighted that nitrofurantoin was previously contraindicated in patients with a creatinine clearance of less than 60 ml/min. The UTI and antimicrobial guidance would need to be updated accordingly and primary care alerted to this very important message.	**SD**
14.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in September. TA 322 Lenalidomide for treating myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality. Lenalidomide classified as a **RED** drug. CG 30.1 Long-acting reversible contraception (update). Mrs Qureshi stated that the progestogen-only sub dermal implant Implanon, previously recommended in this guideline, was no longer available and had been replaced by Nexplanon. The County public health directorate had been contacted about this who had advised that Nexplanon was already being used. CG 183 Drug allergy: diagnosis and management of drug allergy in adults, children and young people. Mrs Qureshi highlighted the section which referred to people who had a mild allergic reaction to a selective NSAID but needed an anti inflammatory. The benefits and risks of selective cyclo-oxygenase 2 (COX 2) inhibitors (including the low risk of drug allergy) should be discussed with the patient together with consideration of the introduction of a selective COX 2 inhibitor at the lowest starting dose with only a single dose on the first day. A drug allergy chart had been produced and put on the Medicines Management website. CG 184 Dyspepsia and gastro oesophageal reflux disease: Investigation and management of dyspepsia, symptoms suggestive of gastro oesophageal reflux disease, or both. Mrs Qureshi reported that the local clinical guideline was being updated in line with the NICE guidance. Mr Dhadli highlighted a change in the dyspepsia H pylori eradication therapy to seven days first line and seven days second line, with the latter not stating strengths or doses. This was at variance with the current guidance and would need to be discussed further with the Acute Trusts. Dr Goddard advised that the RDH H pylori guideline was due for review. CG 185 Bipolar disorder: the assessment and management of bipolar disorder in adults, children and young people in primary and secondary care. DG 14 Atrial fibrillation and heart valve disease: self- monitoring coagulation status using point of care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor). Mrs Qureshi would contact Ms Ann Hayes to	**SD**

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Item		Action
	request a position statement from the Clinical Commissioning Policy Group.	**SQ**
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Umeclidinium/vilanterol (Anoro) – BLACK Lurasidone – RED Lenalidomide - RED	
16.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Fluticasone propionate nasal drops (nasules) – To be brought to the December JAPC meeting. Nortriptyline – To be removed from the list. Vigabatrin – To be brought to the December JAPC meeting. Thiamine – To be brought to the December JAPC meeting.	**SD** **SD** **SD** **SD**
17.	**GUIDELINE GROUP**	
	The Guideline Group action progress summary was noted by JAPC.	
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Chesterfield Royal Hospital Foundation Trust Drugs and Therapeutic Committee 16.9.14	
19.	**ANY OTHER BUSINESS**	
	There were no items of any other business.	
20.	**DATE OF NEXT MEETING**	
	Tuesday, 11th November 2014 at 1.30pm in the Post Mill Centre, South Normanton. The dates of JAPC meetings in 2015 were noted for information.	