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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 11th March 2014

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Alogliptin	UNCLASSIFIED until local diabetes guideline has been produced
Fluticasone furoate plus vilanterol (Relvar Ellipta)	BLACK
Potassium para-aminobenzoate (POTABA)	BLACK
Fentanyl buccal	BROWN
Aflibercept	RED (as per TA305, aflibercept for treating visual impairment caused by macular oedema secondary to CRVO)
Pixantrone	RED (as per TA306, pixantrone monotherapy for treating multiply relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma)

Clinical Guidelines
Out of hours formulary

Misc
JAPC position statement on 28 day prescribing intervals

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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
Dr I Tooley	GP
Mrs L Hunter	Finance
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
Derbyshire County Council	
Mrs S Qureshi	NICE Audit Pharmacist
Derby Hospitals NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutics Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Mrs B Thompson	Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Head of Medicines Management
Derbyshire Community Health Services NHS Trust	
Mr M Steward	Chief Pharmacist
In attendance	
Miss P Chera	Medicines Management Interface Technician

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Item		Action
1.	**APOLOGIES**	
	Dr E Rutter, Dr C Shearer	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	Mrs Qureshi declared a conflict of interest, her husband Dr Nadeem Qureshi is on the guideline development group for NICE lipid guidance	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	Alcohol and substance misuse- Slak Dhadli NOACs – Mr Shepherd	
4.	**MINUTES OF JAPC MEETING HELD ON 11th February 2014**	
	The following amendments were made to the minutes of the meeting held on 11th February 2014: **Page 1** Amorolfine – amend to: *contraindicated or not tolerated* Teriflunomide – amend to: *RED as per NICE TA 303* Clinical Guidelines – amend to: *Bisphosphonate length of treatment guideline in osteoporosis* **Page 3** Nebuliser guideline – amend to: *Deferred to the April JAPC meeting* **Page 5** Minocycline – amend to: *existing patients initiated by secondary care* **Page 9** Fentanyl patches – amend to: *severely harmed or killed* Subject to amendments stated, JAPC agreed they were happy to accept the minutes of the February 2014 meeting	**SD** **SD** **SD** **SD**
5.	**MATTERS ARISING**	
	Medical devices Dr Mott provided some background about discussions had at the previous JAPC meeting around medical devices. Dr Mott informed the group that three areas were selected for further investigation; compression stockings, lymphoedema garments and vacuum pumps. **Compression stockings** Mrs Needham informed the group that after reviewing prescribing data for compression stockings it has come to light that there is a higher proportion of made to measure stockings being prescribed in primary care, 13% in the North and nearer 20% in the South. Mrs Needham advised that made to measure compression stockings are more expensive than standard compression stockings. Mrs Needham suggested that the guidance should include how to prescribe stockings, how often to replace stockings, quantities required. The literature suggests that 5% of stockings will be made to measure. **Agreed:** Guideline group to produce some guidance for the prescribing of compression stockings **Lymphoedema garments** Mr Shepherd informed the group that he is still awaiting a response from Ashgate Hospice. Mr Newman informed the group that he has had a response from Dr Keeley's team at the Royal Derby Hospital. There is no shared formulary for lymphoedema garments but the team are noticing more patients coming to clinic with inappropriate garments.	**Guideline group**

Item		Action
	Historically Dr Keeley's teams have always tried to prescribe from the hospital rather than ask GPs to prescribe. The team are open to discussions around formularies and the best way to prescribe more cost-effectively. **Agreed:** Guideline group to liaise with Dr Keeley to produce some guidance on the provision of lymphoedema garments	**Guideline group**
	Vacuum devices Mr Shepherd confirmed that the Chesterfield Royal Hospital do not use vacuum devices however Mrs Needham highlighted that GPs do receive requests for prescribing these from CRH. Mr Newman informed the group that he is still awaiting a response from RDH urologists. Mr Newman added that he was referred to the Nottingham APC formulary where vacuum devices have been categorised, it was suggested that Mr Dhadli take a look at the Nottingham guidance on vacuum devices.	**SD**
	ADHD shared care guideline **Dexamfetamine** Mrs Thompson informed the group that the old shared care guideline had a dose for children aged 3-5 years which was taken from the Dexadrine SPC which is no longer in existence and is not in the current BNFc. Mrs Thompson confirmed that the CAMHS service and community paediatricians are happy for this to be removed from the shared care guideline because they don't treat this age group. **Agreed:** remove reference to Dexamfetamine use in children aged 3-5 years	**BT**
	Lisdexamfetamine Mr Dhadli queried the inclusion of the unlicensed use of lisdexamfetamine for the treatment of ADHD in adults. Mrs Thompson confirmed that this had specifically been included in the guideline to make it the same as the other drugs included in the guideline. Mr Dhadli informed the group that the trials to consider lisdexamfetamine had only been completed in children and questioned whether GPs would be happy to prescribe a new drug in an unlicensed way. **Agreed:** Mrs Thompson to raise with Dr Taylor	**BT**
	Implementation of the ADHD shared care guideline Dr Emslie informed the group that in North Derbyshire there is a LES being developed for monitoring of all drugs that are not included in the basket of services for which there will be some money attached. Dr Emslie added that because of this LES the North Derbyshire prescribing group didn't think that implementation of the shared care guideline would be an issue. Dr Parkin and Dr Henn confirmed that this is yet to be discussed at their CCG prescribing group meetings. Dr Mott informed the group that implementation of the shared care guideline was discussed at the Southern Derbyshire CCG prescribing group and that GPs on the group were unhappy with the increase in work. The GPs were particularly concerned about monitoring blood pressure in children. Mrs Thompson added that no changes had been made to the monitoring requirements section of the shared care guideline when this was updated. **Agreed:** await feedback from Hardwick CCG and Erewash CCG	**TP/MH**

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6.	NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS	

Alogliptin

Mr Dhadli informed the group that Alogliptin is the 5th gliptin to be launched. Local guidance around all gliptins state that there is poor evidence for their use and other more cost effective options are available. It has been agreed locally to use gliptins in patients to control symptoms of hyperglycaemia and need to avoid hypoglycaemia and are for short term use only.

Mr Dhadli provided some background into the use of gliptins:

a. Instead of sulfonylurea if risk of hypoglycaemia or if sulfonylurea is not tolerated/ contraindicated
b. Instead of metformin if metformin not tolerated or contraindicated
c. As an addition to metformin and sulfonylurea instead of insulin (if insulin is unacceptable/social/employment/recreational)
d. Preferred to pioglitazone if:
   i. Further weight gain is a concern
   ii. Pioglitazone is contraindicated or not tolerated or not effective
e. Patient choice
f. Continue if beneficial i.e. 0.5% drop at six months

Mr Dhadli went on to explain that evidence review come from a new NICE evidence review summary from May 2013. The evidence is primarily from two of the six randomised control trials that are line with current NICE guidance. The studies were generally well designed; a good size and findings are feasible. Dual therapy of alogliptin + metformin was a 26 week randomised control trial which is the Nauck et al study and there was a triple therapy study with alogliptin + metformin + pioglitazone which was a 52 week randomised control trial the Bosi et al study. The outcome data shows an HBA1c reduction of 0.5% which is seen as clinically significant vs placebo. There is a mixed response with the other four randomised controlled trials but roughly around 0.5% in HbA1c reduction.

Mr Dhadli explained that safety concerns around the use of gliptins still remained. In October 2013 a NICE evidence commentary that highlighted the risks which include increased risk of hypoglycaemia and increased risk of admission to hospital due to heart failure with saxagliptin. There was also a RADAR publication from Australia in August 2010 and a RADAR brief in December 2013 which highlighted that the efficacy of gliptins is similar across the class, that the long-term safety of gliptins is yet to be established and also echo JAPCs current view that although side effects are usually mild and transient, there have been post marketing reports of hypersensitivity and pancreatitis.

Mr Dhadli then tabled a summary of all the gliptins highlighting similarities of the drugs and variations in licensing and dosing in renal and hepatic impairment.

Mr Dhadli explained that there is 52 weeks of evidence so far with no long term safety and efficacy although more studies are on-going. Studies show there are no serious safety concerns but there was no statistical testing undertaken for difference in safety outcomes in either of the two main randomised controlled trials.

Mr Dhadli summarised key points for JAPC in their decision making:

a. NICE guidance is expected in August 2015 but alogliptin will not be included in this
b. There are no randomised controlled trials with metformin + sulfonylureas
c. No head to head studies vs the other gliptins
d. Both Bosi et al and Nauck et al had run in periods before randomisation in which 13 and 12%, respectively, of eligible patients were excluded. Both trials used last observation carried forward in their analysis to account for missing data
e. Bosi et al study (non-inferiority and superiority trial)

i. Bosi-et al use a per-protocol data set which can introduce bias. This excluded 25% of those initially randomised into alogliptin triple therapy group.
ii. Treatment allocation concealment was not described
iii. In Bosi et al study HbA1c peaked at week 20 for triple and dual therapy, and there was a trend for increase in hb1ac thereafter that had not levelled off at the end of study which possibly shows a diminishing effect over time

f. Seems effective when used as dual therapy
g. Alogliptin could be accepted on cost minimisation grounds as the cheapest in its class

Dr Mott suggested that alogliptin should remain unclassified until the local diabetes guideline has been approved and that the views of the diabetologists should be sought to see if this drug class could be rationalised with preferred choices.

Agreed: Alogliptin UNCLASSIFIED pending updated diabetes guideline. **SD**

Agreed: Mr Newman to feedback to Dr Game that gliptins require clarity around place in therapy as part of the diabetes guideline update **CN**

Fluticasone furoate plus vilanterol (Relvar) for the treatment of asthma or COPD

Mr Dhadli informed the group that Relvar is a fixed dose combination inhaler of a corticosteroid, fluticasone furoate, and a long-acting beta-agonist licensed for COPD and asthma and is available in two strengths.

Mr Dhadli covered the evidence covering the two licensed indications of the inhaler

Relvar in asthma. This evidence review has come from the RDTC in January 2014. Its use is in adults and children over the age of 12, an advantage is that it is a dry powder used once daily and against some inhalers appears cost effective. Mr Dhadli advised the group that JAPC focus should be on patient safety, there are no proven advantages over established treatments, there is no safety data beyond 52 weeks, the adverse effects are comparable to 500micrograms BD of fluticasone which is equivalent to 2000micrograms of beclometasone, it is restricted to one delivery device and there are four other inhaled corticosteroid and long-acting beta-agonists products available in the UK. There are three double blind phase III studies published in full for people aged 12 years and over treated with an inhaled corticosteroid with or without a long-acting beta-agonist for 12 weeks; participants had to be stable for at least four weeks. One of the studies included those with an exacerbation requiring antibiotics or steroids in the previous 12 months. There was concern of the study design. There was a run in period where non-trial inhaled corticosteroids and long-acting beta-agonists were discontinued which may have de-stabilised asthma control. There was an improvement in trough FEV1 when Relvar was compared with fulticasone furoate and to fluticasone propionate without the long-acting beta agonist. No significant differences in Fev1 change from baseline were observed when Relvar 92/22 daily was compared with fluticasone propionate + salmeterol 250/50.

Mr Dhadli then went on to summarise the evidence for the use of Relvar in COPD. Mr Dhadli explained that this review was from the June 2013 NICE new medicines publication. Relvar is licensed for the symptomatic treatment of adults with COPD and an exacerbation history. The evidence review is from three randomised controlled trials and most of NICEs discussions focus on the Relvar 100/25 inhaler strength. Although exacerbations were reduced there was no statistical difference in the yearly rate of exacerbations requiring hospital admission. The secondary outcomes included statistical improvement in night time awakening and dyspnoea although statistically significant were small in absolute terms and of questionable.
Mr Dhadli in addition noted that the absence of clinical effectiveness versus other licensed inhalers, the safety concerns of using high potency steroids and in particular the pneumonia cases, equivalent doses of Relvar as known and the study design which

	was undertaken across numerous sites. **Agreed:** Relvar classified as a BLACK drug	**SD**
	Potassium para-aminobenzoate (POTABA) Mr Dhadli informed the group that Potaba was listed in the BNF as 'less suitable for prescribing'. In 2012 the product manufacturer wrote to the BNF clinical references relating to the use of Potaba in Peyronie's disease, asking for a review of the symbol denoting less suitable for prescribing. The symbol itself was added to the BNF in 1998 and the references used at the time predated the new ones received from the manufacturer. Based on expert advice received and several clinical papers, the Joint Formulary Committee of the BNF agreed to the deletion of the LSP symbol from Potaba. Mr Dhadli added that a request has been received by a GP from a consultant since the review asking for Potaba to be prescribed for a patient following a private referral. Mr Dhadli summarised the evidence. The evidence outside of non-surgical therapy for oral treatment for Peyronie's disease is limited and low level. Although it is recognised by the European Association of Urology that if Potaba is used early it stabilises the condition and prevents penile curvature, the views of local consultant urologists were that Potaba is not supported or recommended. **Agreed:** Potaba to remain BLACK	**SD**
7.	**CLINICAL GUIDELINES**	
	Lipid modification – NICE draft guideline Mr Dhadli informed the group that NICE have published a draft guidance on lipids, statins and CVD risk. This is currently out for consultation and then final guidance would be published later in the year. The draft guidance if accepted requires significant change to current practice both in primary and secondary care. Examples of key changes: • In preference to Framingham CVD risk should be calculated using QRISK2 • The 10 year CVD risk at which treatment should be offered had been reduced from 20% to 10% • Atorvastatin is the first line statin, using 20mg for primary prevention and 80mg for secondary prevention Mr Dhadli informed the group that he has registered with NICE as a stakeholder and has completed a pro-forma with his comments on behalf of Southern Derbyshire CCG. The proforma was tabled at JAPC highlighting questions and concerns that would be fed back to NICE. Dr Mott added that although JAPC doesn't usually look at consultations this particular update could have a significant impact on GP workload and that GPs should be made aware of this draft guideline and encouraged CCGs and GPs to respond to the consultation. Mr Dhadli questioned whether the lipidologists would want to be involved in discussions around the use of high intensity statins in the primary prevention of CVD. CCGs in Derbyshire were encouraged to register individually as stakeholders of the consultation document **Agreed:** Mr Newman to discuss the use of high intensity statins in primary prevention of CVD with the cardiologists **Out of hours formulary for Derbyshire Health United** Dr Mott informed the group that the Derbyshire Health United out of hours formulary	**CN**

	had been updated with the following: • Addition of ranitidine • Removal of oral diclofenac • Addition of Ulipristal (EllaOne) if used in line with current JAPC guidance **Agreed:** The updated formulary was accepted **Restless Leg Syndrome guidance** Mr Dhadli informed the group that this guideline was developed after queries were received from the medicines management teams around which drugs were recommended for restless leg syndrome. Dr Tooley and Dr Mott asked why the DTB reviews supporting the guidance were contradicting in their recommendations. Mr Dhadli added that he had always been reluctant to produce a guideline due to the lack of high quality evidence. Mr Dhadli was concerned that having a clinical guideline could open up off-licence prescribing for a relatively common primary care condition. The guideline group however felt some guidance was better than none and had drafted this version from Clinical Knowledge Summaries (CKS). Dr Tooley added that having read the guideline as a member of the guideline group, there is no evidence to back up the guideline and doesn't feel it would add anything. Discussion followed and the group felt that although a guideline might be helpful in a very small number of patients, the information is already available on CKS. Dr Mott asked that in future before the guideline group embarked on producing new guidelines JAPC should be informed to assess need. **Agreed:** Guideline was not required and hence not ratified for use.	
8.	**PGDs**	
	None	
9.	**SHARED CARE GUIDELINES**	
	Sulfasalazine Mr Dhadli informed the group that the SPC for sulfasalazine has been updated and that more monitoring is required. Mr Dhadli added that the DMARDs shared care guidelines would need to be updated in line with these changes and the views of the relevant consultants be sought. **Agreed:** To be updated via the guideline group	**SD**
10.	**HORIZON SCAN**	
	Monthly horizon scan The monthly horizon scan had identified fluticasone furoate plus vilanterol inhaler, evidence for this was supplied earlier in the meeting through the new drug assessment. Dr Mott informed the group that a new formulation of Fentanyl is available. It is a buccal film, used for breakthrough pain in cancer patients already receiving opioids. **Agreed:** Fentanyl Buccal film classified as a BROWN drug	**SD**
11.	**MISCELLANEOUS**	
	JAPC statement on 28 day prescribing intervals Mr Dhadli informed the group that this was an update of the old PCT position statement on 28 day prescribing intervals. Mr Hulme suggested that the wording around weekly prescriptions should be strengthened to 'weekly prescriptions should be exceptional and only used if there is a genuine clinical need'. **Agreed:** The position statement was ratified pending minor amendments	**SD**

	High cost drugs in renal transplant Mr Dhadli informed the group that NHS England had distributed a circular about the repatriation of patients receiving immunosuppressive drugs post-transplant to specialist centres. Mr Dhadli added that there may be work for primary care and/or the medicines management teams, to identify these patients. This preparation would ensure seamless transfer of these patients back to specialist centres, as this process should be complete by March 2015. The group questioned where these patients should be repatriated back to and also when the work should begin. **Agreed:** To be raised at the East Midlands Pharmacists meeting	**SH/KN**
12.	**JAPC BULLETIN**	
	Strontium Mr Dhadli informed the group that he has made some changes to the statement about strontium in line with the recent European Medicines Agency advice. The EMA advise that strontium can be used for the treatment of osteoporosis if other medication has failed but should be stopped if patients develop heart or circulatory problems.	
13.	**MHRA DRUG SAFETY UPDATE**	
	Strontium Mr Dhadli informed the group that the European Medicines Agency has distributed a letter recommending that strontium remain available for the treatment of osteoporosis. Mr Dhadli added that the letter suggests regular monitoring of cardiovascular risk. **Agreed:** Update local guidelines to reflect recommendations **Combined Hormonal Contraceptives and venous thromboembolism** Mr Dhadli informed the group that the risk of VTE is small, updated risk factors have been included in the warning.	**SD**
14.	**NICE TEMPLATE**	
	Framework of NICE Guidance Mrs Qureshi informed the group of the comments of the CCGs which had been made for the following NICE guidance issued in February: TA304 Total hip replacement and resurfacing angioplasty for end-stage arthritis of the hip. Mrs Qureshi informed the group that this TA does not have any prescribing implications. TA305 Treatment of visual impairment caused by macular oedema - Aflibercept Mrs Qureshi informed the group that this is a new indication for Aflibercept, costing for each CCG has been included in the framework. **Agreed:** Aflibercept classified as a RED drug TA306 Treating multiple relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma – Pixantrone. Mrs Qureshi informed the group that although this drug comes under specialised commissioning, but it needs to be given a traffic light classification. **Agreed:** Pixantrone classified as a RED drug CG177 Osteoarthritis (OA) Mrs Qureshi informed the group that although this guideline has been updated the pharmacological elements of the guideline are yet to be reviewed. NICE are recommending that until this review takes place the 2008 guidance should be followed for pharmacological treatment. Mr Dhadli added that CG177 has been published on the NICE website and that	**SD** **SD**

	although the pharmacological elements have not been updated NICE are recommending that clinicians should re-consider using paracetamol for osteoarthritis. However Mr Dhadli advised JAPC that this should not change local practice. Paracetamol should still remain first choice in OA based on its safety profile and preference to toxic oral NSAIDs CG178 Psychosis and schizophrenia in adults Mrs Qureshi informed the group that the guideline has some updates that Derbyshire Healthcare Foundation Trust may want to look at and compare to local guidance. **Agreed:** Derbyshire Healthcare Foundation Trust to review and update local guidelines	**BT**
15.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Alogliptin – **UNCLASSIFIED until local diabetes guideline has been produced** Fluticasone furoate plus vilanterol (Relvar Ellipta) – **BLACK** Potassium para-aminobenzoate (POTABA) – **BLACK** Fentanyl buccal film– **BROWN** Aflibercept – **RED** Pixantrone – **RED**	**SD**
16.	**JAPC ACTION SUMMARY**	
	Actinic Keratosis This guidance has been discussed at the RDH Clinical Improvement Group; Dr Goddard to discuss with Dr Bleiker **Metoclopramide in gastro paresis** Dr Goddard is still awaiting a position statement for the long term use of metoclopramide in gastro paresis from the British society of gastroenterology **Agreed:** draft to be available for the April JAPC meeting **Medical devices** CRH are producing a proposal for the use of Therabite jaw devices. Mr Newman queried if Therabite was a new device and how requests for this were being handled. Dr Mott confirmed that this had been around for some time and that it had been classified as red at the previous JAPC meeting.	**WG** **WG**
17.	**GUIDELINE GROUP ACTION TRACKER**	
	The Guideline Group tracker for information. Dr Mott informed the group that Dr Tooley who is the GP representative on the guideline group will be retiring. Dr Emslie has agreed to become the new GP representative on the group.	
18.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Minutes of the DHFT D&T committee – 20/01/2014 • Minutes of the DHCFT D&T committee – 23/01/2014 • Minutes of the medication operational safety team, DCHS – 15/01/2014 • Minute of the Sheffield Area Prescribing Group – 21/01/2014 • Minutes of the Nottinghamshire Area Prescribing Committee – 21/11/2013	
19.	**ANY OTHER BUSINESS**	
	NOACs Mr Shepherd expressed concerns about how NOACs are being used locally and felt that local guidance doesn't reflect where we should be. **Agreed:** Mr Shepherd to put forward a proposal to the JAPC outlining the gaps in the current local guidelines **Alcohol and substance misuse** Mr Dhadli informed the group that there are shared care guidelines in need of updating relating to alcohol abstinence and substance misuse. Mr Dhadli added that he has	**MS**

	tried too many times to ascertain how the alcohol services will be commissioned from the 1st April. It appears that in Derbyshire County the service will be provided by Addaction and in Derby City there doesn't appear to be a tier 3 service which means GPSI's will be relied on to prescribe alcohol related drugs. The substance misuse drugs would also be prescribed through GPSI's who are contracted to DHCFT Dr Emslie added that there are GPs who are not GPSI and not affiliated with DHCFT who prescribe in practice so it would not be safe to remove the shared care guidelines. Mr Dhadli informed the group that Addaction had agreed to update the shared care guidelines for alcohol misuse however no updates have been received; this has been on-going for a number of months. **Agreed:** Substance misuse shared care guidelines to be updated by DHCFT **Agreed:** Dr Mott to write to the City & County public health teams to ask them to update the alcohol misuse shared care guidelines	**BT** **AM**
	DATE OF NEXT MEETING	
	Tuesday 8th April 2014 **Birchwood Room, Post Mill Centre, South Normanton**	