

## **DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)**

### **Minutes of the meeting held on 14<sup>th</sup> November 2017**

## **CONFIRMED MINUTES**

### **Summary Points**

#### **Traffic lights**

<b>Drug</b>	<b>Decision</b>
Dronedarone	AMBER
Cladibrine	RED
Mercaptamine	RED (as per NHS England commissioning intentions)
Brentuximab vedotin	RED (NHS England as per NICE TA 478)
Reslizumab	RED (NHS England as per NICE TA479)
Tofacitinib	RED (as per NICE TA 480)
Basiliximab, Tacrolimus IR and Mycophenolate	RED for adults, children and young people (NHS England as per NICE TAs 481 and 482)
Chloramphenicol ear drops	BLACK

#### **Clinical Guidelines**

Oral Anticoagulation with Warfarin

Pharmacological Treatment of Premature Ejaculation

Prescribing for Oral Thrush in Babies and Prescribing for Surface and Ductal Thrush in Lactating Women

#### **Patient Group Directions**

Administration of low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) to individuals from 10 years of age

Administration of diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (DTaP/IPV or dTaP/IPV) to individuals from three years four months to under ten years of age

#### **Shared Care Guidelines**

Dronedarone for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF)

<b>Present:</b>	
<b>Southern Derbyshire CCG</b>	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Professional Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
<b>North Derbyshire CCG</b>	
Dr C Emslie	GP
Dr T Narula	GP
Mrs K Needham	Assistant Chief Quality Officer (Medicines Management) (also representing Hardwick CCG)
Ms J Town	Head of Finance
<b>Hardwick CCG</b>	
Dr T Parkin	GP
<b>Erewash CCG</b>	
Dr M Henn	GP
<b>Derby City Council</b>	
Dr R Dewis	Consultant in Public Health Medicine
<b>Derbyshire County Council</b>	
<b>Derby Teaching Hospitals NHS Foundation Trust</b>	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
<b>Derbyshire Healthcare NHS Foundation Trust</b>	
Mr S Jones	Acting Chief Pharmacist
<b>Chesterfield Royal Hospital NHS Foundation Trust</b>	
Ms C Duffin	Principal Pharmacist
<b>Derbyshire Community Health Services NHS Foundation Trust</b>	
Mr G Crawshaw	Pharmacist
<b>In Attendance:</b>	
Ms A Brikmanis	Patient Experience and Engagement Manager, North Derbyshire CCG
Ms M Khan	Medicines Information Pharmacist, CRHFT
Ms L Swain	Head of Patient Engagement, North Derbyshire CCG
Mr A Thorpe	Derby City Council (minutes)
Mr J Vinson	Lead Medicines Management Pharmacist, North Derbyshire CCG

Item		Action
<b>1.</b>	<b>APOLOGIES</b>	
	Ms A Braithwaite and Ms J Shaw.	
<b>2.</b>	<b>DECLARATIONS OF CONFLICT OF INTEREST</b>	
	<p>Dr Mott reminded committee members of their obligation to declare any interest they may have on any issues arising at committee meetings which might conflict with the business of JAPC.</p> <p>No conflicts of interest were declared in relation to this agenda; in addition to the existing register of interests.</p>	
<b>3.</b>	<b>DECLARATIONS OF ANY OTHER BUSINESS</b>	
	There were no declarations of any other business.	
<b>4.</b>	<b>MINUTES OF JAPC MEETING HELD ON 10 OCTOBER 2017</b>	
	<p>The minutes of the meeting held on 10<sup>th</sup> October 2017 were agreed as a correct record after the following amendments:</p> <p>Azithromycin Eye Drops – Amend to: ‘Agreed Azithromycin eye drops classified as GREEN 3<sup>rd</sup> line for bacterial conjunctivitis if chloramphenicol and gentamicin is contraindicated (e.g. pregnancy) or not tolerated, as suitable for primary care prescribing.</p> <p>Gluten Free Food Prescribing – Amend to: ‘Gluten free foods had been available on prescription for more than forty years and during that time the cost of GF foods to purchase had significantly reduced.’          Amend to: ‘Change the gluten-free allowance to eight units per month for everyone eligible for gluten-free food on prescription and have much more limited products available on prescription’.          Amend to: ‘Dr Goddard commented that the landscape of the NHS had now changed, with increased awareness of the prevalence of coeliac disease, greater access to gluten free foods and the thresholds for diagnosis of coeliac disease had significantly increased.’</p> <p>Biosimilar Task and Finish Group – Amend to Biosimilar Working Group.</p>	
<b>5.</b>	<b>MATTERS ARISING</b>	
<b>a.</b>	<b><u>ADHD Monitoring in Adults</u></b>	
	Dr Mott confirmed that the concern about the lack of a diagnostic service had been conveyed to the commissioners and would now go via the commissioning process.	
<b>b.</b>	<b><u>Bariatric Surgery</u></b>	
	Mr Dhadli reported that a link to the East Midlands Bariatric and Metabolic Institute page had been added to the guideline and the Sheffield Teaching Hospital had a bariatric surgery page which included patient information, referrals and resources for health care professionals.	
<b>6.</b>	<b>JAPC ACTION SUMMARY</b>	
	The action summary was noted by JAPC and amendments made:	

Item		Action
	<p>NRT and service provision – To be discussed at today’s meeting.</p> <p>ADHD monitoring in adults – To be taken off the list.</p> <p>Biosimilar Working Group – To be taken off the list.</p> <p>Suspected DVT NOAC/D-dimer – To be brought to the December 2017 JAPC meeting.</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
<b>7.</b>	<b>NEW DRUG ASSESSMENTS</b>	
<b>a.</b>	<p><b><u>Methylnaltrexone bromide</u></b></p> <p>Mrs Qureshi reported that the current traffic light classification for Methylnaltrexone was BROWN after consultant/specialist recommendation and it had been re-classified from red to allow palliative care patients timely access to the drug in 2011. It would be necessary to consider whether the current traffic light classification for methylnaltrexone should be changed following the termination of NICE TA 468 ‘Methylnaltrexone bromide for treating opioid-induced constipation’ in August 2017. Methylnaltrexone was indicated for the treatment of opioid-induced constipation when the response to laxative therapy had not been sufficient in adult patients aged eighteen years and older.</p> <p>No substantial new evidence had been published since the original review. The London New Medicines Group (LNMG) in 2008 had indicated that up to 90% of cancer patients on chronic opioid therapy would suffer with bowel dysfunction and most patients who received any opioid would also require laxative treatment. A number of studies had been undertaken and a Phase II study had demonstrated that, when methylnaltrexone was given with morphine, gut transit times were reduced to those of baseline levels. The analgesic effects of morphine had not been compromised by the use of methylnaltrexone. There had been two phase III studies: Study 301 had evaluated the efficacy of a single dose of methylnaltrexone (0.15mg/kg or 0.30mg/kg) compared with placebo. This had been followed by an open label four-month study where methylnaltrexone could be used PRN up to once every 24 hours. Bowel movements had occurred faster, and in more patients, in the methylnaltrexone groups, compared with placebo. Study 302 had involved methylnaltrexone 0.15mg/kg or placebo given every other day during a double-blind 2-week phase and then followed by a three-month open-label extension study. It was noted that bowel movements occurred significantly faster and more often in the methylnaltrexone group. The LNMG had concluded that approximately half of the patients responded to methylnaltrexone with bowel movements occurring within four hours of the dose. In December 2008 the SMC had recommended methylnaltrexone for the treatment of opioid-induced constipation in advanced illness and for patients receiving palliative care when response to usual laxative therapy had not been sufficient.</p> <p>Mrs Qureshi reported that information had been received from a CRHFT consultant that the TA had not been terminated due to lack of evidence but because the company who currently owned the licence had decided not to submit.</p>	

Item		Action
	<p>However the evidence for the effectiveness of the drug was robust and this had been confirmed in clinical practice. The drug was also not a significant cost pressure due to limited prescribing. In use in a community setting it probably prevented more expensive admissions to hospital for faecal impaction and therefore a classification of BROWN would be desirable for exceptional use. It was noted that there was very little use in the south of Derbyshire.</p> <p><b>Agreed:</b> Methylnaltrexone to remain classified as <b>BROWN</b> after palliative care consultant/specialist recommendation due to exceptionality where a small cohort of patients may benefit from prescribing can be identified.</p>	SD
<b>8.</b>	<b>CLINICAL GUIDELINES</b>	
a.	<p><b><u>Oral Anticoagulation with Warfarin</u></b></p> <p>Mr Dhadli reported that the guideline had been updated with minor changes following comments received from CRHFT. It had been queried whether it was necessary to add a further resource of training using the MHRA e-learning. The British Medical Journal module, which required registration, was recommended but it was queried whether the MHRA e-learning module as used at CRHFT could be added. Mr Dhadli was unsure whether this met the National Patient Safety Agency (NPSA) competencies so advised that until confirmed the BMJ should be the source of education and competency. Dr Henn queried the common warfarin drug interactions in table 4 which included two references to herbal preparations/food – this would be made clearer in the sections which listed the drugs that increased or decreased the INR.</p> <p><b>Agreed:</b> JAPC ratified the Oral Anticoagulation with Warfarin guideline with the agreed amendments with a two year review date.</p>	SD  SD
b.	<p><b><u>Dapoxetine</u></b></p> <p>Mr Dhadli reported that dapoxetine was the first licensed treatment available in the UK to treat premature ejaculation (PE) in 18 to 64 year olds. Dapoxetine was a rapidly acting Selective Serotonin Re-Uptake Inhibitor (SSRI) and there had been other SSRIs which had been used off-label but these had longer onset of action to reach efficacy and also required continuous daily dosing. JAPC had classified dapoxetine as BLACK in December 2013.</p> <p>Mr Dhadli commented that it had been anticipated that there would be significant interest in this licensed treatment for PE but there had in fact been very few queries on the subject and very little prescribing. The guideline had now been updated with current prices and the title of the guideline amended to 'Pharmacological treatment of premature ejaculation' with the inclusion of the position statement on dapoxetine on page 3. Mrs Needham questioned the relevance of the statement in the dapoxetine position statement that it would only be revised following relevant Department of Health national direction – it was agreed that this should be removed.</p> <p><b>Agreed:</b> JAPC ratified the Pharmacological Treatment of Premature Ejaculation guideline with the agreed amendment with a two year review date.</p>	SD  SD

Item		Action
c.	<p><b><u>Nicotine Replacement Therapy Formulary</u></b>            Dr Dewis reported that from 1<sup>st</sup> December 2017 the Live Life Better Derbyshire Services, which included smoking cessation, would be provided by Derbyshire County Council. The Nicotine Replacement Therapy (NRT) formulary provided guidance to primary care on the prescribing of NRT. Mrs Needham queried whether all available NRT products needed to be included in the formulary. It was noted that Derby City had a much smaller range of NRT products. The Guideline Group had advised that there should be a more restricted formulary with the inclusion of the most cost-effective products as first, second and third line choices. Dr Mott referred to the issue concerning re-charging of the NRT products prescribed by GPs. Mrs Needham stated that the County Council would procure the products, which were given directly to people, and it may be necessary to re-consider the traffic light classifications in the event that the re-charges were not accepted. Mr Dhadli added that the need for extra precautions concerning the use of the drug clozapine and smoking cessation had been highlighted in the NRT protocol together with the necessity of ensuring that DHcFT was informed before any changes were made.</p> <p><b>Agreed:</b> JAPC approved the Derbyshire Formulary for Nicotine Replacement Therapy (NRT) of the service.</p> <p><b>Action:</b> Dr Mott would discuss the issue of re-charging with Dean Wallace, Derbyshire County Council Director of Public Health.</p> <p><b>Action:</b> Mr Dhadli would produce an abridged version of the NRT formulary for use by GPs.</p>	<p><b>SD</b></p> <p><b>AM</b></p> <p><b>SD</b></p>
d.	<p><b><u>Oral Thrush in Babies</u></b>            Mr Dhadli reported that the existing guideline had been updated by the infant feeding team. The guideline had been developed in the light of a MHRA warning about the use of miconazole oral gel in children under four months of age because of the risk of choking. A review had subsequently been undertaken by the Breastfeeding Network and guidance produced on the most effective medication for oral thrush in infants. This advice had been added into additional guidance to include surface and ductal thrush in lactating women. Page 2 of the guideline had been updated in line with the guidance together with the advice to continue application with miconazole oral gel for seven days after resolution of symptoms. It was highlighted in the guidance that miconazole oral gel for infants was the most effective product for oral thrush with the caveat that its use for babies under four months was off-licence and required careful application.</p> <p><b>Agreed:</b> JAPC ratified the Prescribing for Oral Thrush in Babies and Prescribing for Surface and Ductal Thrush in Lactating Women with a two year review date.</p>	<p><b>SD</b></p>
<b>9.</b>	<b><u>PATIENT GROUP DIRECTIONS</u></b>	
	<p>The following PGDs from NHS England were noted by JAPC:</p> <ul style="list-style-type: none"> <li>Administration of low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) to individuals from 10 years of age.</li> </ul>	

Item		Action
	<p>This would be effective from 1<sup>st</sup> November 2017.</p> <ul style="list-style-type: none"> <li>Administration of diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (DTaP/IPV or dTaP/IPV) to individuals from three years four months to under ten years of age. This would be effective from 1<sup>st</sup> December 2017.</li> </ul>	
<b>10.</b>	<b>SHARED CARE GUIDELINES</b>	
<b>a.</b>	<p><b><u>Dronedarone</u></b>          Mr Dhadli reported that a draft shared care agreement had been developed for the use of dronedarone as an option for the maintenance of sinus rhythm after successful cardioversion in people with paroxysmal or persistent atrial fibrillation (AF) - the views of the DTHFT/CRHFT cardiologists had been sought on this. Dronedarone had previously been assigned a traffic light classification of RED due to the monitoring requirements. It was reported that there had been some use in secondary care of dronedarone in Derbyshire with thirty-four patients at DTHFT and six at CRHFT. The proposed shared care had previously been discussed by JAPC and the ECG monitoring, which was required every six months, had been highlighted as a potential issue. GP members of JAPC and the CCG Prescribing Groups had expressed the view that undertaking ECGs and interpreting the results should remain in secondary care. Mrs Needham suggested that GPs should be consulted about the ECG component of the shared care agreement before approval was given to the shared care. It would be highly important that GPs received confirmation that the ECG monitoring had been carried out and the test results were satisfactory. Mrs Needham also queried the reference in the monitoring requirements to the consultant assuming responsibility for the first twelve months of treatment. It should be clarified that the consultant would retain overall responsibility for the patient and the prescribing for the first twelve months. After this time the ECG monitoring would remain a consultant responsibility but the blood monitoring and prescribing could then be requested to be taken over by the GP. This was agreed by JAPC.</p> <p><b>Agreed:</b> The dronedarone shared care guideline for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF) was ratified with the agreed amendments. Dronedarone classified as AMBER.</p>	<p><b>SD</b></p> <p><b>SD</b></p>
<b>11.</b>	<b>MISCELLANEOUS</b>	
<b>a.</b>	<p><b><u>JAPC Terms of Reference</u></b>          Mr Dhadli referred to the amended terms of reference and changes made:</p> <ul style="list-style-type: none"> <li>JAPC will have oversight of the working groups and receive regular feedback on their work.</li> <li>There will be an annual conflicts of interest declaration at the start of each year in January which will be recorded in a register.</li> <li>Chairs should consider any known interests of members in advance and begin each meeting by asking for declaration of relevant interests.</li> <li>If a member has an actual or potential interest the chair should consider the following approaches and ensure that the reason for the chosen action is documented in minutes or records:             <ul style="list-style-type: none"> <li>➤ Requiring the member to not attend the meeting.</li> </ul> </li> </ul>	

Item		Action
	<ul style="list-style-type: none"> <li>➤ Ensuring that the member does not receive meeting papers relating to the nature of their interest.</li> <li>➤ Requiring the member to not attend all or part of the discussion and decision on the related matter.</li> <li>➤ Noting the nature and extent of the interest, but judging it appropriate to allow the member to remain and participate.</li> <li>➤ Removing the member from the group or process altogether.</li> </ul> <ul style="list-style-type: none"> <li>• JAPC will review and have oversight of the work plan and decisions made by the guideline group (operational function of JAPC).</li> </ul> <p>It was suggested that a reference to the Regional Medicines Optimisation Committees should be added to the terms of reference in the stakeholder map – this was agreed.</p> <p>In connection with membership Mr Hulme referred to the lack of a quality representative - Dr Mott would discuss a possible representative with Jayne Stringfellow, Chief Nurse and Director of Quality of the Derbyshire CCGs. Mr Hulme added that the membership may need to be reviewed due to the impending move to a single Derbyshire CCG management structure. Dr Mott also referred to the wider issue of lay representation on JAPC which would need to be addressed. Mr Dhadli would amend the list of JAPC named representatives with the correct email addresses and circulate for comment.</p>	<p><b>SD</b></p> <p><b>AM</b></p> <p><b>SD</b></p>
<p><b>b.</b></p>	<p><b><u>Prescribing Specification</u></b></p> <p>Mr Dhadli reported that the Prescribing Specification has been updated for 2018/19 with the following amendments/additions:</p> <ul style="list-style-type: none"> <li>• Communication with patients and responding to queries.</li> <li>• Outpatient attendance: provider organisation requirements.</li> <li>• Discharge: provider organisation requirements.</li> <li>• High Cost Drugs excluded from Tariff commissioned by CCGs – Introduction of biosimilar medicines and the need to follow the principles laid out in the NHS England Commissioning Framework for biological medicines together with timelines and targets.</li> <li>• Biosimilar Gain Share.</li> </ul> <p>In addition communication had been received from Mr Newman and Mr Shepherd about home care and the need to adhere to the national key performance indicators.</p> <p>Mr Newman requested that the phrase ‘procedures will be in place’ replace the reference to the treating clinician in the paragraph in section 11 ‘The treating clinician will ensure that the patient is aware to obtain non-FP10 prescriptions from the outpatient pharmacy service and not to request a GP transcription onto FP10.’ This was agreed by JAPC.</p> <p><b>Agreed:</b> JAPC ratified the Derbyshire JAPC Prescribing Specification 2018-2019 with the agreed amendments and additions.</p>	<p><b>SD</b></p> <p><b>SD</b></p>
<p><b>c.</b></p>	<p><b><u>Withdrawal of Bovine Insulin</u></b></p> <p>Dr Mott informed JAPC that bovine insulin would be discontinued in the UK which would mean that those diabetic patients using this form of insulin would need to change to a new treatment.</p>	



Item		Action
	<p>Dr Mott had liaised with the DTHFT diabetologists who had advised that this would not be a straightforward switch and patients would therefore need to be repatriated to specialist care for this to occur. The advice followed the Diabetes UK publication which identified these patients as 'High Risk' and that transition should be undertaken by a diabetes multidisciplinary team. This process had now commenced with the small number of patients involved.</p> <p><b>d. <u>Doxycycline Position Statement</u></b>          Mr Dhadli reported that Public Health England and the British Association for Sexual Health and HIV (BASHH) had produced a position statement which stated that doxycycline post exposure prophylaxis (PEP) for sexually transmitted infections was not endorsed by either organisation. The use of antibiotics as prescribed by a healthcare professional and as indicated by the results of a suitable diagnostic test was recommended instead. It was likely that any potential benefits of doxycycline PEP could be outweighed by the unknowable risks associated with widespread, unprescribed and unmonitored use of a tetracycline antibiotic. Dr Dewis advised that sexual health clinics had been made aware of the position statement and highlighted that there were a number of online services for HIV who could be using doxycycline PEP in this way.</p> <p><b>e. <u>Gluten Free Prescribing</u></b>          Mr Hulme stated that JAPC had been requested to review the recommendation made at the October meeting to restrict the number of gluten free products to four units per month for adults and children and provide greater clarification as to the rationale for this and why other options, such as full decommissioning, had been discounted. JAPC would therefore need to make a Derbyshire-wide recommendation, to be conveyed to the governing bodies of the four CCGs, which was evidence based and followed the framework process which the committee used for making informed decisions.</p> <p>Mr Hulme continued by stating that it would be necessary to consider, in the same way as would be done with a drug or treatment, an active comparator. This could be gluten free foods purchased over the counter, a natural gluten free diet without supplementation or something else. Mr Hulme's personal view was that a gluten free natural diet should be the comparator. Mr Dhadli advised that the comparator should be gluten free products off-prescription and gluten free products on prescription as that was the option being applied through the consultation. Dr Goddard considered that coeliac patients needed a gluten free diet and therefore the comparator would be a normal gluten containing diet. Mrs Needham stated that the recommendation made at the last JAPC meeting to restrict to four units had not been based on any good evidence but rather an attempt to mitigate some of the concerns raised such as access, affordability and results from the national consultation. Dr Mott highlighted that JAPC had previously made a consensus recommendation to restrict to four units in the light of the conflicting opinions which had been expressed during the discussion. A request had subsequently been received for greater clarification as to the reasons for that recommendation and therefore the JAPC decision making framework would be applied and an evidence based recommendation made if possible and, if this could not be done, the views which had been expressed by members would be conveyed to the CCG governing bodies.</p>	

Item	Action
<p>It was highlighted that JAPC was not set up to respond to consultations.</p> <p>Discussion followed and points made:            Safety and Clinical Effectiveness - Mr Vinson advised that there was evidence to indicate that coeliac children who did not follow a gluten free diet were more at risk of development issues including restricted growth. It was important that they should follow a gluten free diet but there was no evidence to demonstrate that obtaining this food on prescription would encourage them to adhere to this. JAPC could highlight this lack of evidence to the CCG governing bodies and that there was no method to measure the clinical impact of removing gluten free prescriptions in the timescale where any adverse effects could be measured. The available evidence had not been obtained from randomised trials but mainly via patient questionnaires and there was a consequent lack of cause and effect. JAPC therefore concluded that there was a lack of evidence to indicate that children's growth would be affected.</p> <p>There was some evidence that members of Coeliac UK were better at adherence to a gluten free diet. This could be due to the fact that these were patients keen to do this and that membership aided their adherence. In connection with gluten free prescriptions there were some studies, but not all, which indicated that this would assist with adherence. However this could be due to the keen patients who adhered to the diet and had sufficient knowledge to enable them to obtain gluten free on prescription. There were others who were less motivated and lacked the information that gluten free food could be obtained via prescription – this had been reflected in some of the consultation feedback. In addition, there was a lack of information as to what constituted a full month's supply of gluten free food apart from the Coeliac UK guidelines. Mr Hulme added that it would seem to be the case that adherence to a gluten free diet, whether or not obtained via prescription, could be enhanced by the ability to process information. There was an American study which had looked at adherence to a gluten free diet and the possible factors which contributed to this of cost, perceived effectiveness, perceived knowledge and perceived self-awareness. All four contributed to adherence but the main two with the strongest correlation were perceived knowledge and perceived self-effectiveness.</p> <p>Cost Effectiveness – It was noted that the total spend on gluten free products in Derbyshire was currently £750,000 per year and that these were more expensive to the NHS per unit price than if purchased from shops or supermarkets. The current pressures on NHS budgets and the local high expenditure on gluten free products were highlighted. In addition, there could be additional on-costs, such as out of pocket, to the NHS. Gluten free products were generally more expensive than gluten containing equivalents as food and natural GF foods. Purchases by patients could lead to reduced waste and over ordering.</p> <p>Patient Factors – The difficulties which may be encountered by some communities with access to gluten free food had been highlighted during the previous discussion at the October JAPC meeting. Mr Dhadli stated that this had been identified in the equality impact assessment (EIA) which referred to mitigating factors such as the availability of on-line preparations and alternative ordering methods.</p>	

Item		Action
f.	<p>Income had also been mentioned as a potential significant issue but was not a protected characteristic under the Equality Act 2010. However mitigation was provided by access to information and resources about obtaining gluten free foods on a budget. Ms Brikmanis commented that the EIA outlined the actions which would be implemented in the event that any decision was made to stop gluten free altogether and mitigation put in place to counter the negative aspects of such a decision. Anecdotal feedback had been obtained from an individual living in an isolated community in Derbyshire who had referred to the need to rely on friends and family to purchase gluten free food and, if this was not available on prescription, he would have a significant problem. It would therefore be necessary to ensure that something was in place for these groups of vulnerable people. Dr Goddard commented that there were people with low incomes who were used to having a diet of cheaper foods as they lacked sufficient monies to purchase more expensive fruit and vegetables. In the event that these people had to go on to a gluten free diet they would find it difficult to purchase due to the increased cost. They were also more likely to have long term health problems in addition to coeliac disease. Dr Henn commented that coeliac disease was a medical condition with a recognised treatment and queried whether there was a group of patients who would not be able to access this in the event that gluten free prescriptions were withdrawn. Mr Vinson referred to one CCG which had implemented a restricted formulary and had then sent questionnaires to GPs and patients over the course of a year to query any problems and whether there had been an increase in the number of patients accessing primary care. Approximately 25% of these patients had indicated that their diets had become less healthy than previously and GPs had reported no changes to the number of referrals.</p> <p>Mr Hulme highlighted that patient factors, and the mitigation of these, were the main issue in any decision by JAPC to confirm the previous recommendation or make an alternative one. Dr Emslie stated that people on low incomes were less likely to access and respond to advice from dietitians and would either purchase low cost 'value' items such as bread or use bread on prescription. Dr Henn highlighted that the mitigation seemed to be aimed at educated people and not everyone had online access or could understand any information and advice provided. Mr Hulme queried whether there was anything else which would determine that gluten free should be put on prescription, if mitigation had been put in place for all of the patient factors, or was the issue just about patient factors.</p> <p><b>Agreed:</b> JAPC agreed to recommend to the CCG governing bodies that the number of gluten free units should be limited to four per month for adults and children together with a restricted formulary, or to stop gluten free prescribing altogether if sufficient mitigations to the patient factors on access could be identified.</p> <p><b><u>Self-Care Policy</u></b>          Mr Vinson explained that over £3,000,000 was spent by the four CCGs in Derbyshire on prescription items which could be purchased over the counter by patients. However it was very difficult to determine whether the proportion of these prescriptions issued were for short-term or long-term conditions.</p>	SH/AM

Item	Action
<p>It had been therefore decided to undertake a public consultation across Derbyshire for a period of ten weeks to ascertain whether people would be prepared and expected to purchase their own medicines, for short-term minor health conditions, from shops, supermarkets and other outlets instead of via prescriptions. JAPC noted that three options had been included in the consultation:</p> <ul style="list-style-type: none"> <li>• Support stopping NHS prescriptions for medicines to treat common minor conditions that were suitable for self-care for all patients;</li> <li>• Do not support stopping NHS prescriptions for medicines to treat common minor conditions that were suitable for self-care for all patients; and</li> <li>• Support stopping NHS prescriptions for medicines to treat common minor conditions that were suitable for self-care for most people but that prescribing should continue in specific circumstances or for specific conditions.</li> </ul> <p>The consultation results had revealed that the overwhelming majority (92%) of patients supported the stopping of prescribing for minor conditions; although a significant number (54%) had wanted exceptions for specific groups of patients or conditions such as vulnerable groups and low income. Other potential issues of concern had been highlighted such as recurrent conditions, risk of mis-diagnosis and that minor symptoms could mask more serious conditions. Some responders had also suggested the need for patient education. It was reported that measures had been included in the consultation report in order to mitigate against some of these concerns.</p> <p>Mr Vinson stated that the Self-Care Policy had been developed to ensure that the prescribing of medicines and treatments available to purchase over-the-counter, and used for the treatment of minor, short-term medical conditions or had little evidence of benefit, was stopped. However the Derbyshire Local Medical Committee (LMC) had advised that contractually GPs may be obliged to prescribe if it was felt that a patient required a certain medication and he or she were adamant that they wanted a prescription. In the event that it was felt to be clinically beneficial for GPs to issue a prescription then this would be a matter of clinical judgement. This would be a mitigating factor in covering the concerns which had been raised about the impact on vulnerable groups such as the homeless and there would also be an ongoing patient education campaign to address seasonal related ailments such as influenza and hayfever. JAPC was requested to discuss make a Derbyshire-wide recommendation to be conveyed to the governing bodies of the four CCGs which would then make final decisions.</p> <p>Discussion followed and points made:        Dr Henn referred to the statement in the Policy to the professional discretion of the GP concerning an individual patient. Dr Henn commented that every patient was an individual and therefore a reference was needed about exceptional circumstances, in addition to individuality, when the general policy was applied in order to prevent pressure being put on GPs to use their discretion in favour of the patient. Dr Watkins highlighted an issue when schools could demand prescriptions from primary care. Dr Mott advised that the County and City Councils had adopted a position to indicate that this was not necessary but it would be up to the schools to make individual policies.</p>	

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g.	<p>Dr Watkins also referred to potential similar issues with nursing homes and the Medical Administration Record sheets.</p> <p>Dr Mott stated that the system-wide policy was intended to reinforce the ability of GPs to reject requests for prescriptions for short-term conditions but, if this indicated that prescriptions could still be issued for individuals, then the position of GPs would be greatly undermined. It would be necessary to define exceptionality but the policy would need to support GPs in the messages which were given. This would also cover the advice given by the LMC concerning the contractual obligations of GPs. Mr Hulme referred to the Presc-QIPP position in Cambridge about self-care and the discussions with the General Medical Council concerning the obligations of GPs. The Cambridge policy had now been implemented so it would be useful to look at what had been done and the references to exclusion criteria. Mr Vinson added that a number of neighbouring CCGs had put similar self-care policies in place and therefore Derbyshire would not be an outlier.</p> <p><b>Agreed:</b> JAPC agreed to recommend to the CCG governing bodies the Derbyshire-wide Self-Care Policy.</p> <p><b>JAPC Meeting Room</b>            It was noted that JAPC would no longer meet at the Post Mill Centre with effect from the January 2018 meeting. The new venue would be Coney Green Business Centre, Wingfield View, Clay Cross, Derbyshire.</p>	<p><b>JV</b></p> <p><b>SH/AM</b></p>
<b>12.</b>	<b>REGIONAL MEDICINES OPTIMISATION COMMITTEE (RMOC)</b>	
	<p>Mr Dhadli reported that the Regional Medicines Optimisation Committee (North) had reviewed the use of the flash glucose monitoring system, Freestyle Libre®. RMOC had recommended to Area Prescribing Committees that, until further trial data was available, audit data on the use of Freestyle Libre® be collected through its use in limited and controlled settings where patients were attending for Type 1 diabetes care. RMOC had also indicated the types of patients who may be eligible for Freestyle Libre® and the stop criteria. It was noted that Freestyle Libre® had been classified as BLACK at the October JAPC meeting with a view that it would re-consider this position following a business case and proposal by the local diabetologists.</p>	
<b>13.</b>	<b>JAPC BULLETIN</b>	
	<p>The bulletin was tabled for information and ratified by JAPC.</p>	
<b>14.</b>	<b>MHRA DRUG SAFETY UPDATE</b>	
	<p>The MHRA Drug Safety Alert for October 2017 was noted.            Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> <li>• Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40 mg) not to be used in patients with cows' milk allergy.</li> <li>• Gabapentin (Neurontin®): risk of severe respiratory depression.</li> <li>• Isotretinoin (Roaccutane®): rare reports of erectile dysfunction and decreased libido. This had been classified as RED by JAPC.</li> <li>• Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction and paralytic ileus.</li> </ul>	

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	This had been included in the clozapine guidance and BNF chapter.	
<b>15.</b>	<b>HORIZON SCAN</b>	
	<p><b>Monthly Horizon Scan</b>            Mr Dhadli advised JAPC of the following new drug launches and new drug formulations:</p> <p>New drug launches in the UK:            Autologous human corneal epithelial cells (Holoclar®) - Already classified as RED (TA 467).            Cladribine (Mavenclad®) – Classified as <b>RED</b> as per NHS England commissioning intentions. NICE TA expected in February 2018.</p> <p>New formulation launches in the UK:            Mercaptamine (Cystadrops®) – Classified as <b>RED</b> as per NHS England commissioning intentions.            Raltegravir (Isentress®) – No action as already classified as <b>RED</b>.</p> <p><b>Quarterly NICE Updates</b>            Mr Dhadli referred JAPC to the NICE horizon scan and highlighted the following:            Clinical Guidelines:</p> <ul style="list-style-type: none"> <li>• Glaucoma: diagnosis and management (update). This had already been published and was broadly in line with the JAPC guidance which recommended a PF prostaglandin analogue first line and a PF beta-blocker as second line.</li> <li>• Familial hypercholesterolaemia (FH). There had been a partial update which included genetic testing for FH, currently available at CRHFT, with a proposal to extend to DTHFT.</li> </ul> <p>Asthma – NICE guidance had been due to be published on 31<sup>st</sup> October but had been delayed. Mrs Qureshi advised that NICE intended to publish two sets of guidance to cover diagnosis and monitoring. The monitoring guidance would include a reference to the promotion of leukotrienes and LABAs and the monitoring guidance to the measurement of the amount of forced exhaled nitric oxide in the breath. Advice had been received from a DTHFT respiratory consultant who had been contacted about the latter, which was seen as a specialist area for secondary care, although a few referrals had been received from GPs.</p>	
<b>16.</b>	<b>NICE SUMMARY</b>	
	<p>Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in October 2017.</p> <p>TA 477 Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee – Not classified (NHS England).</p> <p>TA 478 Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma – Classified as <b>RED</b> (NHS England).</p> <p>TA 479 Reslizumab for treating severe eosinophilic asthma – Classified as <b>RED</b> (NHS England).</p>	

Item		Action
	<p>TA 480 Tofacitinib for moderate to severe rheumatoid arthritis – Currently classified as <b>BLACK</b> and re-classified to <b>RED</b> as per TA. To be added to the RA commissioning algorithm.</p> <p>TA 481 Immunosuppressive therapy for kidney transplant in adults and TA 482 Immunosuppressive therapy for kidney transplant in children and young people - Basilixiab, tacrolimus IR and mycophenolate all recommended – all classified as <b>RED</b> (NHS England).</p> <p>NG 78 Cystic fibrosis: diagnosis and management. Mrs Qureshi advised that most of the drugs referred to in the guidance had already been assigned traffic light classifications.</p>	
<b>17.</b>	<b>GUIDELINE GROUP ACTION TRACKER</b>	
	<p>The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in October 2017 was noted. Mr Dhadli highlighted the following:</p> <p>Atropine eye drops – Classified as <b>GREEN</b>. It was noted that the 1% preservative free minims was the cost effective formulation over the 10ml eye drops.</p> <p>Chloramphenicol ear drops – The Guideline Group had given a traffic light classification of <b>BROWN</b> specialist recommendation as NICE CKS did not recommend chloramphenicol ear drops as they contained propylene glycol which caused contact dermatitis in about 10% of people. ENT consultants had been contacted to ascertain their views on its place in therapy and Dr S Mortimore had advised that there was no reason to use chloramphenicol ear drops over more cost effective products which were available. There was also a risk of using chloramphenicol eye drops in error.</p> <p>Mefenamic acid – The Guideline Group had classified mefenamic acid as <b>BROWN</b> for use in patients with dysmenorrhoea and menorrhagia where other nonsteroidal anti-inflammatory (NSAID) drugs had been ineffective. Mr Dhadli advised that the NICE Clinical Guidelines on endometriosis and heavy menstrual bleeding referred to the use of any of the NSAID drugs. Concern was expressed at the high cost of mefenamic acid which was licensed for the treatment of dysmenorrhoea. This would be brought back to the December JAPC meeting for further discussion of the licensing issue and the advice given in the NICE guidelines.</p> <p>Insulin lispro (Humalog®) 200u/ml – Classified as <b>BROWN</b> in the light of the MHRA warning issued in April 2015 about the higher risk of medication error with high strength, fixed combination and biosimilar insulin products.</p> <p>DMARD Monitoring Guidelines – Amended to handover when monitoring was stable monthly (for three months) and three monthly monitoring (or as per schedule).</p>	<b>SD</b>

Item		Action
	<p>Metformin in pre-diabetes – Advice from Public Health England had been added to the Derbyshire BNF endocrine chapter.</p> <p>NSTEMI South – This would be extended to March 2018 as the prasugrel patent price reduction was awaited before discussion commenced with the cardiologists.</p> <p>C.Difficile – A Public Health England update was awaited in December 2017.</p>	
<b>18.</b>	<b>TRAFFIC LIGHTS – ANY CHANGES?</b>	
	<p><b><u>Classifications</u></b></p> <p>Dronedarone – <b>AMBER</b></p> <p>Cladibrine – <b>RED</b></p> <p>Mercaptamine – <b>RED</b> (as per NHS England commissioning intentions)</p> <p>Brentuximab vedotin – <b>RED</b> (NHS England as per NICE TA 478)</p> <p>Reslizumab – <b>RED</b> (NHS England as per NICE TA479)</p> <p>Tofacitinib – <b>RED</b> (NHS England as per NICE TA 480)</p> <p>Basiliximab, Tacrolimus IR and Mycophenolate – All <b>RED</b> for adults, children and young people (NHS England as per NICE TAs 481 and 482)</p> <p>Chloramphenicol ear drops – <b>BLACK</b></p>	
<b>19.</b>	<b>MINUTES OF OTHER PRESCRIBING GROUPS</b>	
	<ul style="list-style-type: none"> <li>• CRHFT Drugs and Therapeutic Committee 19/09/2017</li> <li>• DTHFT Drugs and Therapeutic Committee 19/09/2017</li> <li>• DCHSFT Medication Optimisation Safety Team (MOST) 05/10/2017</li> </ul> <p>Mr Dhadli highlighted the following from the DCHSFT MOST minutes:</p> <ul style="list-style-type: none"> <li>• A new drug request had been submitted for the use of botulinum toxin for anal fissures. However Mr Dhadli advised that NICE and the Drugs and Therapeutic Bulletin did not support its use for this indication. Ms A Braithwaite, DCHSFT Head of Medicines Management, would be contacted about this.</li> </ul>	<b>SD</b>
<b>20.</b>	<b>ANY OTHER BUSINESS</b>	
	There were no items of any other business.	
<b>21.</b>	<b>DATE OF NEXT MEETING</b>	
	Tuesday, 12 <sup>th</sup> December 2017 at 1.30pm in the Post Mill Centre, South Normanton.	