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

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 8th March 2016

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Dymista nasal spray	BROWN specialist initiation
Beclomethasone 50mcg nasal spray (as beconase)	GREEN 1st line
Mometasone 50mcg nasal spray (generic)	GREEN 2nd line
Budesonide 64mcg nasal spray	GREEN 3rd line
Fluticasone furoate nasal spray as Avamys	GREEN 3rd line
Cobimetinib	RED (NHS England)
Efmoroctocog alfa	RED (NHS England)
Follitropin alfa biosimilar (Ovaleap)	RED
Mepolizumab	BLACK (pending expected TA in July 2016)
Methoxyflurane	RED
Dental fluoride products	RED for specialist dental services (not recommended for GPs to prescribe)
Adalimumab	RED as per NICE TA 383
Certolizumab	RED as per NICE TA 383
Etanercept	RED as per NICE TA 383
Golimumab	RED as per NICE TA 383
Infliximab	RED as per NICE TA 383
Nivolumab	RED as per NICE TA 384
Ezetimibe	Remains BROWN as per NICE TA 385

Clinical Guidelines

Bisphosphonate length of treatment guideline in osteoporosis (treatment holiday).
Cellulitis class II treatment pathway for use by DCHS Rapid Response Team and Integrated Community Based Services.
New guidance for the use of Dymista in patients with allergic rhinitis.

Shared Care Guidelines

Immunomodulating drugs: azathioprine/6-mercaptopurine, ciclosporin, leflunomide, D-penicillamine, sodium aurothiomalate and sulfasalazine.

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (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
North Derbyshire CCG	
Dr C Emslie	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Ms J Town	Head of Finance
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Dr R Dewis	Consultant in Public Health Medicine
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair - Drugs and Therapeutic Committee
Derbyshire Healthcare NHS Foundation Trust	
Ms S Bassi	Chief Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Mr M Steward	Head of Medicines Management
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	APOLOGIES	
	Mr C Newman.	
2.	DECLARATIONS OF CONFLICT OF INTEREST	
	No declarations of interest were made.	
3.	DECLARATIONS OF ANY OTHER BUSINESS	
	<ul style="list-style-type: none">• Future of Clinical Policy Group.	
4.	MINUTES OF JAPC MEETING HELD ON 9 FEBRUARY 2016	
	The minutes of the meeting held on 9 th February 2016 were agreed as a correct record after the following amendment: Traffic Lights – Amend to read Vortioxetine.	
5.	MATTERS ARISING	
a.	<p><u>Dental Prescribing</u></p> <p>Mr Dhadli stated that PrescQIPP had first produced a list (previously called Drugs of Low Priority) in 2012 which was an accumulation of medicines that were considered as low priority, poor value for money or for which there were safer alternatives. This list had now been updated and incorporated drugs prescribed across the NHS that were considered low priority and poor value for money and also some of the NICE 'do not do' items. In January 2015 a DROP-List concerning medicines for dental conditions on FP10 had been produced which recommended that GPs should not accept requests from dentists to prescribe medicines. A query had been received from the Charles Clifford Dental Hospital in Sheffield which highlighted that there could be a group of vulnerable patients who may not be registered with a dental practitioner and therefore would need to continue to have their dental products prescribed. JAPC had discussed this at the February 2016 meeting and it had been agreed that the evidence should be looked at before any decision was made concerning a change to the traffic light classification. Mr Dhadli advised that dental products were referred to in a NICE Clinical Knowledge Summary (CKS) under self-care for palliative care use and in the NICE CG 'Dental checks: intervals between oral health reviews'. The General Dental Council (GDC) Guidance on Prescribing Medicines highlighted that remote means should only be used to prescribe medicines for dental patients if there was no other viable option and it was in their best interests.</p> <p>Mr Dhadli referred to the position in Sheffield where some allowance had been made for GPs to prescribe and a brief guidance had been produced to recommend the dental products which they could continue to prescribe. Sheffield Local Medical Committee had also advised that there may be some exceptional circumstances where dental products could be prescribed for patients with genuine health vulnerabilities. Greater Huddersfield CCG did not generally recommend the prescribing of dental products but had produced a list of exceptional circumstances where GPs could prescribe. Greater Manchester CCG did not allow any prescribing of dental products by GPs due to the risk of fluorosis and East Kent CCG had advised that patients should self-care with over the counter preparations.</p>	

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	<p>Mr Steward referred to correspondence sent by the DCHSFT Specialist in Special Care Dentistry which had expressed concern that there were occasions when nursing and residential homes did not always make requests for repeat prescriptions to the dental clinic and therefore GPs were occasionally requested to take on some repeat prescribing. A traffic light classification of RED rather than BLACK would therefore be preferable in order for the specialist dental service to take on the prescribing themselves.</p> <p>During discussion it was noted that there were 1700 dental items prescribed by GPs annually, primarily in North Derbyshire, at an approximate annual cost of £12,000. Dr Parkin and Dr Henn highlighted that GPs were not trained to issue prescriptions for dental products and deal with the risk of complications. In addition, other items could also be included, such as fluoride mouthwash, in addition to fluoride toothpaste and that there could be a risk that this prescribing could extend to other areas which GPs should not be responsible such as optical products.</p> <p>Agreed: Fluoride Dental products classified as RED for specialist dental services use only. GPs are not recommended to prescribe fluoride products.</p>	SD
b.	<p><u>Management of Sub-Therapeutic INR in Medical Patients</u></p> <p>Mr Dhadli reported that the Guideline Group had been requested to look at the management of those patients who had a sub-therapeutic International Normalised Ratio (INR) and the use of low molecular weight heparins (LMWH) for this. It was noted that there was no national guidance and a decision had been made to go out to consultation. Ms A Braithwaite, CRHFT Principal Pharmacist Clinical Services, had advised that there was an internal protocol which could be amended for more general use if GPs wished. This protocol highlighted that the use of LMWH to manage sub-therapeutic INRs was standard practice in CRHFT Acute Trust. It also referred to the risk stratification of high risk and standard risk patients together with the consideration of aspects such as actual body weight, renal function and bleeding risk amongst others. Mr Dhadli added that Dr A McKernan, DTHFT Consultant Haematologist, had advised that the table in the CRHFT protocol would open up prescribing for LMWH for a wider population when this was not always desirable and was not evidence based. Dr Mott highlighted the need for a clear consensus about the use of LMWH and the potential for a significant increase in costs and workload for GPs and practice staff. It would be important to provide guidance for those providers in general practice and also for the community pharmacists who delivered the service to patients in the community. It was noted that the ACCP had issued guidance on LMWH and there were guidelines from the British Committee for Standards in Haematology (BCSH) on oral anticoagulation with warfarin but the only reference to sub therapeutic INR was for one group of patients in the first month after acute VTE.</p> <p>Action: Dr Mott and Mr Dhadli would develop some questions for Ms Braithwaite and Dr McKernan in order to try and achieve consensus on effectiveness, safety, cost and patient factors.</p>	AM/SD

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Item		Action
c.	<p><u>Ulipristal</u> Mr Dhadli reported that Ms J Parratt, CRHFT Consultant Gynaecologist, had developed a shared care pathway for the prescription of Ulipristal Acetate for symptomatic fibroids in pre-menopausal women. During discussion Dr Emslie commented that the heavy menstrual bleeding guidelines made it clear that tranexamic acid, contraceptive pill (if indicated) and intrauterine system (if indicated) should have been tried before any referral to hospital. It was assumed that these would have been tried but this was not fully indicated in the pathway. Dr Mott highlighted that it would be crucial to obtain the views of the DTHFT gynaecologists on its place in therapy before any decision was made.</p> <p>Action: Mr Shepherd would ascertain the position of the CRHFT gynaecologists.</p> <p>Action: A single document would be developed by the Guideline Group and a traffic light classification for ulipristal acetate for the management of fibroids subsequently assigned by JAPC.</p>	<p>MSh</p> <p>SD</p>
d.	<p><u>Heart Failure Guidance</u> Mr Dhadli stated that the guidance on the management of chronic heart failure with left ventricular systolic dysfunction had expired in October 2014 and it had been queried whether it had been sent to both providers for comment. Mr Dhadli added that only one response had been received to date from the DCHS specialist nurses. Dr Goddard would contact the DTHFT consultant cardiologists directly for their views.</p>	<p>WG</p>
6.	<p>NEW DRUG ASSESSMENTS</p>	
a.	<p><u>Medical Devices</u> Mr Dhadli reported that the East of England Priorities Advisory Committee (PAC) had produced a guidance statement on medical devices 'Evidence review and commissioning recommendations for specified medical devices'. It would be advantageous to peer review the recommendations in this guidance statement with the summary of JAPC recommendations for the commissioning of specified medical devices. Mr Dhadli highlighted that the only differences in the East of England document were:</p> <ul style="list-style-type: none"> • The East of England PAC did not recommend sterimar, a normal saline nasal spray, and this had not been classified by JAPC. It was agreed that the Guideline Group would discuss this further. • MolluDab, 5% potassium hydroxide solution, was not recommended by the East of England PAC but JAPC had assigned a traffic light classification of RED for specialists and GPs specially trained in dermatology and dermatology champions. 	<p>SD</p>
b.	<p><u>PCKS9 Inhibitors</u> Mr Dhadli referred to the East of England PAC Evidence and DTB review on the PCSK9 inhibitors: alirocumab and evolocumab and highlighted some key points:</p>	

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	<ul style="list-style-type: none"> • Evolocumab and alirocumab were the first two proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors in the UK. Twenty more PCSK9 inhibitors were currently in development. • NICE had issued a re-drafted technology appraisal which did recommend evolocumab with restricted use. • There is limited data available regarding cardiovascular events, particularly in relation to hospitalisation rates and mortality and morbidity rates. • Statins had been the primary drugs for the prevention and treatment of hypercholesterolaemia and reduced LDLc levels. However there was still a large cohort of patients in whom LDLc levels were not lowered enough or who could not tolerate a statin. • There was a lack of data for both alirocumab and evolocumab and in all the trials a large number of patients had been pre-excluded. • The DTB review noted that a meta-analysis, which included an open-label extension study, concluded that compared to placebo PCSK9 inhibitors reduced the incidence of all-cause mortality but not cardiovascular mortality or cardiovascular events. • NICE TAs for both evolocumab and alirocumab were due to be published in April 2016 and June 2016 respectively. • There would be a Patient Access Scheme for evolocumab. <p>Mr Dhadli advised that the cardiologists and lipidologists had been asked for their views as part of the horizon scanning process but nothing further was known at this stage.</p> <p>Agreed: Evolocumab and alirocumab would be left classified as BLACK pending NICE TAs.</p>	SD
7.	CLINICAL GUIDELINES	
<p>a.</p> <p>b.</p>	<p><u>Bisphosphonate Treatment Holidays Guidance</u></p> <p>Mr Dhadli advised that the main change to the guidance, made after consultation with the consultant rheumatologists, was that the majority of patients who were deemed 'high risk' after ten years of treatment with bisphosphonates would benefit from a drug 'holiday'.</p> <p>Dr Mott commented that the Prescribing Groups would need to do some work to support GPs when drug treatments were stopped, switched or suspended temporarily. Mrs Needham suggested that a reference to what should be done in primary care be included in the re-assessment box in the flowchart.</p> <p>Agreed: JAPC ratified the bisphosphonate length of treatment guideline in osteoporosis (treatment holiday) guidance with the agreed amendment.</p> <p><u>Cellulitis</u></p> <p>Mr Dhadli reported that the existing guideline had been updated in consultation with Dr Diane Harris, Lead Antimicrobial Pharmacist, and Dr Wijitha Weerakoon, DCHSFT Infection Prevention and Control Specialist. One of the main changes made concerned the flowchart on page 12 when for a patient body weight under 70kg the antibiotic teicoplanin dose had been changed to initially 800mg I.V stat then 400mg once daily starting 24 hours later.</p>	<p>SD</p> <p>SD</p>

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c.	<p>Mr Steward explained that the change had been made to align this with the dosing practice at Royal Derby Hospital and to make the administration by the Rapid Response Team much simpler compared to the previous regime.</p> <p>Agreed: JAPC ratified the Cellulitis Class ii treatment pathway for use by the DCHS Rapid Response Team and Integrated Community Based Services.</p> <p>Dymista Mr Dhadli explained that some further amendments had been made to the referral guide for allergic rhinitis for adults and adolescents over twelve years of age as the skin prick and blood tests had now been placed at the end of the treatment pathway and it had been clarified when GPs would be expected to prescribe. Some comments had been received from Dr Mortimore, DTHFT ENT Consultant, who had suggested the retention of mometasone/fluticasone nasal sprays and from Dr Midwinter, CRHFT ENT Consultant, who had advised against the use of budesonide nasal spray due to its high absorption into the bloodstream. Mr Dhadli advised that all of the 1st line and 2nd line intra-nasal corticosteroids had been listed together with their current traffic light status. In addition, all the corticosteroids nasal sprays had been listed by drug costs for 28 days.</p> <p>Dymista nasal spray was a combination nasal spray of two existing products, fluticasone 50mg and azelastine 137mcg, for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid was not considered sufficient. It had received a traffic light classification of BLACK in June 2013. A DTB summary had concluded that it was marginally more efficacious compared with either azelastine or fluticasone alone and the SMC had reviewed its original decision and now accepted the use of Dymista.</p> <p>Agreed: Beclomethasone nasal spray (as beconase) classified as GREEN 1st line. Mometasone 50mcg nasal spray classified as GREEN 2nd line drug. Dymista is BROWN after Specialist Initiation. All other nasal sprays are GREEN 3rd line in order of cost.</p>	SD
d.	<p>Midodrine Mr Dhadli advised that midodrine had been assigned a traffic light classification of BROWN after consultant/specialist initiation and dose titration for orthostatic hypotension by JAPC in December 2015. Dr Youde, DTHFT Consultant in Medicine for the Elderly, had agreed to develop some guidance for primary care prescribers as those patients who had autonomic failure were likely to have multiple problems and would therefore need to be closely managed within a clinic setting. The revised advisory guidance on the prescribing for midodrine for orthostatic hypotension was noted by JAPC but it was agreed that no decision could be made as there were currently two versions.</p> <p>Action: The guidance would be discussed by the Guideline Group and brought back to JAPC for further consideration.</p>	SD

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8.	SHARED CARE	
	<p><u>Immunomodulating Drugs</u></p> <p>Mr Dhadli reported that it had been necessary to review and update the immunomodulating drugs shared care guidelines. Mr Dhadli advised that the following shared care guidelines had been reviewed by the CRHFT and DTHFT Consultants and highlighted some of the amendments which had been made:</p> <ul style="list-style-type: none"> • Azathioprine/6-Mercaptopurine - The frequency of monitoring of FBC and LFT in the local SCG differed slightly from the British Society for Rheumatology (BSR) guidance. It had been agreed to continue with the local guideline as the dose would be stable in virtually all patients within six weeks. There would be monthly monitoring for the stable patients and then after six months this would decrease to three monthly. Advice had been included concerning the administration of the shingles vaccine after consultant recommendation in line with the national immunisation programme only. • Ciclosporin – In the event of no clinical response at maximum tolerated dose for three months then treatment should be withdrawn. Blood pressure: the local SCG did not include BP parameters as per BSR ($\leq 140/90$) two weeks apart. The consensus was to include parameters as GPs would need to know when to take action. Raised creatinine: $>50\%$ from baseline on a single occasion not in the BSR guidance. Consensus to keep in as per BNF. • Leflunomide - Weight monitoring: The BSR suggested that weight should be monitored at each visit and this was not included in the local SCG. The consensus was to stick with the local SCG. It was noted that leflunomide could cause weight loss but the expectation was that this would be reported by the patient. This, together with the need to inform clinicians if starting a family was planned, to be included in patient responsibilities section of the SCG. Hypertension: consider wash-out in severe cases in consultation with the consultant. • D-penicillamine – Pre-treatment assessment section and action to be taken in case of nausea added. • Sodium aurothiomalate – Addition in patient responsibilities reference to rash and mouth ulcers. Pre-treatment assessment added to monitoring requirements section. Action to be taken added if 2+ proteinuria or more. • Sulfasalazine – No major changes but monitoring requirements to be clarified. <p>Action: The methotrexate shared care guideline to be brought to the April 2016 JAPC meeting.</p> <p>Action: JAPC ratified the shared care guidelines for azathioprine/6-mercaptopurine, ciclosporin, leflunomide, D-penicillamine, sodium aurothiomalate and sulfasalazine with the agreed amendments and two year extensions.</p>	<p style="text-align: right;">SD</p> <p style="text-align: right;">SD</p>

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9.	MONTHLY HORIZON SCAN	
	<p>Mr Dhadli advised JAPC of the following new drug launches, new drug formulations, licence extensions and drug discontinuations:</p> <p>New drug launches in the UK: Albiglutide (Eperzan) – Weekly GLP1 To be considered in the review of local diabetes guidance. Cobimetinib (Cotellic) – NHS England, Classified as RED. Efmoroctocog alfa (Elocta) – NHS England. Classified as RED. Follitropin alfa biosimilar – XM 17 (Ovaleap) – Classified as RED. Mepolizumab (Nucala) – NHS England. Classified as BLACK until the TA was published in July 2016. Methoxyflurane (Penthrox) – Classified as RED.</p> <p>New formulation launches in the UK: Abatacept autoinjector (Orencia) – Already classified as RED.</p>	<p>SD SD SD SD</p>
10.	MISCELLANEOUS	
a.	<p><u>ABPI Sponsorship</u></p> <p>Mr Dhadli stated that information on the Association of the British Pharmaceutical Industry (ABPI) website referred to the need to increase transparency of the relationships with all healthcare professionals (HCPs) and healthcare organisations (HCOs) which was a Europe wide initiative. The European Federation of Pharmaceutical Industries and Associations (EFPIA) had a Disclosure Code which was a formal code of conduct that required all EFPIA member companies, and the companies which are members of EFPIA member associations, to disclose transfers of value to HCPs and HCOs. Under the Code there would be a requirement for public disclosure of certain payments to individual HCPs and HCOs from 2016 for payments which had been made in 2015. There would be a central database to record the types of activities that needed to be disclosed such as conflicts of interest. The aim would be to ensure greater transparency about processes and decision making. It was highlighted that this would apply to all HCOs, to cover areas such as payments and conflicts of interest, and its impact on primary care would need to be determined. Pharmaceutical companies would use a central database to disclose payments and this would go live by 1st July 2016 and be accessible to everyone via the ABPI website.</p> <p>Action: Information about the Disclosure Code would be highlighted via the prescribing groups and other relevant groups within the Trusts.</p>	SD
b.	<p><u>Area Prescribing Committees Event Feedback</u></p> <p>Mr Dhadli reported that he had attended an Area Prescribing Regional Workshop on 25th February 2016 at which the findings of the Pharmacy Management research into the operation of Area Prescribing Committees had been presented. Discussions had been held as to how Area Prescribing Committees could work more effectively. Mr Dhadli highlighted the following subjects which had been discussed at the workshop:</p>	

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Item		Action
c.	<ul style="list-style-type: none"> • Patient/public involvement. • Feedback from Safety Committees to Area Prescribing Groups. • Appeals process – It had been noted that a review should be held in the light of any new evidence and, if due process had not been followed, then this would be the basis of an appeal. It was agreed that these amendments should be made to the Derbyshire JAPC appeals process. <p>Discussion followed on patient/public involvement and Dr Mott highlighted that the current absence of any public or patient representation on JAPC was a significant gap and referred to the previous role on JAPC of the Non-Executive Directors (NEDs) and subsequently Healthwatch Derbyshire represented by Dr Carolin Shearer. Dr Mott suggested that representation from Healthwatch on JAPC could be further explored as there may be new members with a particular expertise or there could be other organisations from which meaningful involvement could be obtained. Mr Hulme commented that patient/public involvement could either include membership on JAPC or obtain assurance that their views had been taken into account during the decision making process. Dr Mott would contact Healthwatch in order to discuss whether a representative from the organisation would be able to undertake the responsibilities involved in the patient/public role on JAPC.</p> <p>In connection with feedback from Safety Committees Mrs Needham advised that terms of reference for a Derbyshire-wide Safety Committee were being developed and circulation of the minutes of these meetings to JAPC could be included in these. Mrs Needham would ensure that the terms of reference of the Derbyshire-wide group when it is established will be made available to a JAPC meeting in order that they could be discussed in conjunction with the JAPC terms of reference.</p> <p>Mr Hulme highlighted that it would be important to avoid duplication as specific safety-related incidents were currently reported via the Drugs and Therapeutic Committees and the prescribing groups. However, in the event that a safety related incident led to a request to change policies or practice, then this would need to be brought to the attention of JAPC.</p> <p>Mr Dhadli referred to the letter received from Dr Keith Ridge, NHS England Chief Pharmaceutical Officer, addressed to the Regional Medical Directors of Midlands and East, South, North and London. The letter outlined the need to establish Regional Medicines Optimisation Committees to help eliminate unnecessary duplication of effort and instead refocus scarce resources towards implementation activities and the achievement of best value and patient outcomes from all medicines via the implementation of medicines optimisation. JAPC noted the letter for information and further information would be made available as received.</p> <p><u>Azithromycin</u> Mr Dhadli stated that an email had been received from within the region following a transcription error from a consultant to a GP regarding the dosing of azithromycin for prophylactic respiratory infection.</p>	<p style="text-align: center;">SD</p> <p style="text-align: center;">AM</p> <p style="text-align: center;">KN</p>

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<p>d.</p> <p><u>Biosimilars – BSG Update</u></p> <p>e.</p> <p><u>Meningitis B</u></p> <p>f.</p> <p><u>Out of Hours Formulary</u></p>	<p>Mrs Needham commented that it would be useful if a reference to a specific dosage of azithromycin could be included in the formulary or guideline in order to indicate that the dose was used in the local Trust and all over the country as the dose in this particular case had not been a licensed dose and therefore not in the BNF.</p> <p>Mr Dhadli reported that the British Society of Gastroenterology (BSG) had issued guidance on the use of biosimilar Infliximab CT-P13 in Inflammatory Bowel Disease. The BSG had concluded that there was sufficient data from observational studies to indicate that the safety and clinical efficacy of biosimilar Infliximab CT-P13 was comparable to the originator drug with similar immunogenicity and that a switch from Remicade to biosimilar Infliximab CT-P13 was also safe and effective. Dr Goddard stated that any medicine switches needed to be discussed with the patient and there was a potential problem with home Infliximab patients who received Remicade. The contractual arrangements concerning the delivery of this by the homecare companies would also need to be looked at. Dr Mott highlighted that JAPC fully supported the use of these agents and encouraged the maximisation of benefits arising from their use.</p> <p>JAPC noted the email received from Sarah Mayfield, NHS England (North Midlands) Screening and Immunisation Manager, which referred to a briefing letter concerning the petition for the government to extend the Meningitis B vaccination programme to all infants including those born before May 2015.</p> <p>JAPC noted that the Derbyshire Health United (DHU) formulary had been reviewed and clarithromycin 500 mg tablets had been added as approved by JAPC in January 2016.</p>	
<p>10.</p>	<p>JAPC BULLETIN</p>	
	<p>The revised bulletin was ratified by JAPC.</p> <p>Dr Mott highlighted that dabigatran, which was the second line choice of NOAC, now had a reversal agent although the other first line NOACs, rivaroxaban and apixaban, did not at present. This raised the question as to whether dabigatran should be promoted in preference to rivaroxaban and apixaban. Following discussion it was agreed the NOAC guidelines to be updated accordingly to reflect that a reversal agent was now available for this NOAC.</p>	<p>SD</p>
<p>11.</p>	<p>MHRA DRUG SAFETY UPDATE</p>	
	<p>The MHRA Drug Safety Alert for February 2016 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> • Valproate and of risk of abnormal pregnancy outcomes: new communication materials. The local guideline would be updated accordingly. • Spironolactone and renin-angiotensin system drugs in heart failure: 	

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	<p>risk of potentially fatal hyperkalaemia. This would be highlighted to the consultant cardiologists when the heart failure guidance was updated.</p> <ul style="list-style-type: none"> Letters sent to healthcare professionals in January 2016 about safety information for Fingolimod (Gilenya): risks related to effects on the immune system and Erlotinib (Tarceva): first-line maintenance indication now restricted to patients with a tumour that has an EGFR-activating mutation. 	
12.	NICE SUMMARY	
	<p>Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in February 2016:</p> <p>TA 383 TNF-alpha inhibitors for ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nrAS) – The CCGs were the responsible commissioner for the drugs: adalimumab, certolizumab, etanercept, golimumab and infliximab. These were classified as RED drugs for AS. In addition adalimumab, certolizumab and etanercept were classified as RED drugs for nrAS. There were now two further drug treatment options for AS: certolizumab and infliximab.</p> <p>The following points were highlighted:</p> <ul style="list-style-type: none"> Previous stipulation of two NSAIDs taken sequentially had changed to patient’s disease had responded inadequately to or who cannot tolerate NSAIDs. Baseline markers of BASDAI and spinal pain VAS were not mentioned in the update. If more than one treatment was suitable, the least expensive one should be chosen. Patients whose disease stopped responding after initial response had the option to try another TNF inhibitor. <p>No significant costs were expected for the AS patient group as a result of the update but significant costs were expected for the nrAS patient group.</p> <p>TA 384 - Nivolumab for treating advanced (unresectable or metastatic) melanoma. Classified as a RED drug (NHS England).</p> <p>TA 385 - Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia – This replaced TA 132 and a traffic light classification of BROWN had previously been assigned. No resource impact was anticipated as the recommendations had not significantly changed from the previous NICE guidance. Classified as a BROWN drug.</p>	<p>SD SD</p> <p>SD</p> <p>SD</p>
13.	TRAFFIC LIGHTS – ANY CHANGES?	
	<p>Classifications</p> <p>Dymista – BROWN specialist initiation</p> <p>Beconase – GREEN 1st line choice</p> <p>Mometasone (generic) – GREEN 2nd line choice</p> <p>Budesonide – GREEN 3rd line choice</p> <p>Avamys – GREEN 3rd line choice</p> <p>Albiglutide – Await diabetes review</p>	

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

Item		Action
	Cobimetinib – RED (NHS England) Efmoroctocog alfa – RED (NHS England) Follitropin alfa biosimilar – RED Mepolizumab – BLACK pending expected TA in July 2016 Methoxyflurane – RED Dental products – RED for specialist dental services Adalimumab – RED as per NICE TA 383 Certolizumab – RED as per NICE TA 383 Etanercept – RED as per NICE TA 383 Golimumab – RED as per NICE TA 383 Infliximab – RED as per NICE TA 383 Nivolumab – RED as per NICE TA 384 Ezetimibe – BROWN as per NICE 385	
14.	JAPC ACTION SUMMARY	
	The action summary was noted by JAPC and amendments made: Immunomodulating drugs – Methotrexate to be brought to the April JAPC meeting. LMWH bridging guidance – Further work to be undertaken by Dr Mott and Mr Dhadli. Ulipristal for uterine fibroids – Guideline Group to develop a single document. Diabetes Type 2 guidance – To be brought to the April JAPC meeting. Heart Failure – To be brought to the April JAPC meeting. Dental prescribing – To be taken off the list. Dr Parkin highlighted the need to be clear that primary care would not pick up prescribing of any dental products.	<p style="text-align: center;">SD</p> <p style="text-align: center;">AM/SD</p> <p style="text-align: center;">SD</p> <p style="text-align: center;">SD</p> <p style="text-align: center;">SD</p> <p style="text-align: center;">SD</p>
15.	GUIDELINE GROUP ACTION TRACKER	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in February 2016 was noted.	
16.	MINUTES OF OTHER PRESCRIBING GROUPS	
	DTHFT Drugs and Therapeutic Committee 19/01/16	
17.	ANY OTHER BUSINESS	
	Dr Mott highlighted that the Derbyshire Clinical Policy Group had not been working effectively for a period of time which had led to delays in the development of clinical policies. Dr Mott also referred to the East Midlands Specialist Policy Group which was being re-instated and that the Derbyshire CCGs had been requested to participate in this. However there was still a need for a local policy group and Mr Hulme advised that scoping work was to be undertaken in conjunction with the City and County Public Health Directorates about what was needed across the local health economy.	
18.	DATE OF NEXT MEETING	
	Tuesday, 14 th April 2015 at 1.30pm in the Post Mill Centre, South Normanton.	