

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 8th November 2016

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Nefopam	BLACK
Pitolisant (Wakix®)	RED (NHS England)
Turoctocog alfa (NoveEight®)	RED (NHS England)
Elbasvir/grazoprevir	RED as per TA 413 (NHS England)
Cobimetinib in combination with vemurafenib	BLACK as per NICE TA 414 (NHS England)
Certolizumab pegol	RED as per NICE TA 415
Osimertinib	RED as per NICE TA 416 (NHS England)

Clinical Guidelines

Oxygen (extension to January 2017)

Patient Group Directions

North Derbyshire MSK service:

Methylprednisolone Acetate 40 mg/ml

Derbyshire Health United:

Amoxicillin

Codeine

Doxycycline

Erythromycin

Ibuprofen suspension

Ibuprofen tablets

Nitrofurantoin

Paracetamol suspension

Paracetamol tablets

Phenoxymethylpenicillin tablets

Chlorphenamine suspension

Chlorphenamine tablets

Clarithromycin

Erythromycin

Flucloxacillin

Prednisolone 5mg tablet

Salbutamol 100mcg inhaler.

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	Assistant Chief Quality Officer (Medicines Management) - 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	
Derbyshire County Council	
Derby Teaching Hospitals NHS Foundation Trust	
Dr W Goddard	Chair - Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Ms S Bassi	Pharmacist
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Foundation Trust	
Ms J Shaw	Principal Pharmacist
In Attendance:	
Ms J O'Connor	Team Supervisor, Derby City Council
Mr A Thorpe	Derby City Council (minutes)
Ms V Twigg	Medicines Management Technician, Southern Derbyshire CCG

Item		Action
1.	APOLOGIES	
	Dr R Dewis and Dr T Narula.	
2.	DECLARATIONS OF CONFLICT OF INTEREST	
	<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>JAPC members were reminded about the necessity of returning their conflict of interest forms to Mr Dhadli.</p> <p>No declarations of interest were made.</p>	
3.	DECLARATIONS OF ANY OTHER BUSINESS	
	No declarations of any other business were made.	
4.	MINUTES OF JAPC MEETING HELD ON 11 OCTOBER 2016	
	<p>The minutes of the meeting held on 11th October 2016 were agreed as a correct record after the following amendments:</p> <p>Addition of Asparaginase recombinant (Spectrila®) as RED (NHS England) to traffic lights list on the cover sheet.</p> <p>Atrial Fibrillation – 'Dr Emslie commented that a previous recommendation had been made that initiation should not necessarily be done by a consultant cardiologist.'</p> <p>Management of Lower Urinary Tract Infection (UTI) in Chronic Kidney disease (CKD) – Review of Existing Guideline – Amend to 'Dr Henn referred to the prescribing of nitrofurantoin in connection with a national quality target for CCGs to reduce blood borne, particularly e-coli infections.'</p>	
5.	MATTERS ARISING	
a.	<p><u>Sayana Press</u> Dr Mott advised that the Derby City Council Public Health department had now decided to develop a protocol for Sayana Press® and this would be brought to the December JAPC meeting.</p> <p><u>Atrial Fibrillation</u> Mr Dhadli stated that guidance was still awaited from the manufacturer of edoxaban as to whether ideal or actual bodyweight should be used as part of the factors to determine dosing and monitoring.</p> <p><u>Pregnant Women and Neonates in Contact with Measles</u> Mr Dhadli reported that Dr Diane Harris would contact Dr Henn in response to the point which had been raised at the meeting about contacts with Nottingham as it was understood that Derbyshire patients should contact the local microbiology departments of either DTHFT or CRHFT.</p>	

Item		Action
d.	<p><u>Naltrexone</u> Dr Taylor would be requested to update JAPC on the lack of consultation in relation to the transfer of responsibilities from GPSs to GPs at the next meeting.</p>	SD
e.	<p><u>Somatropin (Recominant Human Growth Hormone)</u> A reply was awaited from Dr Tracy Tinklin, DTHFT Consultant Paediatrician, as to whether there were more cost effective versions of the somatropin injection. This would be placed on the JAPC action tracker for an update at the next meeting.</p>	SD
f.	<p><u>NICE Summary – NG65 Multi-morbidity: Clinical Assessment and Management</u> Mr Dhadli referred to the discrepancy between the advice given by NICE that patients with osteoporosis should have a bisphosphate 'holiday' for at least three years and that from the National Osteoporosis Society which recommended a period of five years. Dr Roger Stanworth, Consultant Rheumatologist, had been contacted and advice given that the common view of the osteoporosis clinicians was that the current periods should be retained at present.</p>	
g.	<p><u>Nitrofurantoin and Renal Impairment</u> It had been queried at the last JAPC meeting whether the advice given in the MHRA Drug Safety Update of September 2014, that a short course of nitrofurantoin could now be used with caution in certain patients with an eGFR of 30 to 44 ml/min/1.73m², should be included in the guideline for the management of lower urinary tract infection in chronic kidney disease. Mr Dhadli reported that Dr Diane Harris, Lead Antimicrobial Pharmacist, had consulted with local consultant microbiologists, pharmacists and nephrologists across Derbyshire and the general opinion had been given that nitrofurantoin should only be used as a last resort in patients with an eGFR of 30 to 44 ml/min/1.73m². Concerns had been highlighted about a lack of effectiveness of nitrofurantoin in renal impairment and that eGFR was not an accurate method of estimating renal function. Nitrofurantoin was not therefore recommended for routine use rather than by exceptional use. Dr Mott suggested that a reference could be included in the guidance to indicate that nitrofurantoin could occasionally be used but only after microbiologist advice had been obtained. It was agreed that this statement be included in the guideline for the management of lower urinary tract infection in chronic kidney disease.</p>	SD
h.	<p><u>Administration of Vaccinations by DCHSFT Nursing Staff</u> Mr Dhadli reported that it had now been agreed that the administration of vaccinations could be undertaken by DCHSFT nursing staff via a patient specific direction (PSD).</p>	
6.	NEW DRUG ASSESSMENTS	
a.	<p><u>Nefopam</u> Mr Dhadli advised JAPC that there had been a very significant increase in the price of nefopam which was a category C drug in the drug tariff.</p>	

Item	Action
<p>It would be necessary to review the position of nefopam in the formulary and a comprehensive literature review had therefore been undertaken by Knowledge Services. The literature review had highlighted the following:</p> <ul style="list-style-type: none"> • For chronic pain the Scottish Intercollegiate Guidelines Network (SIGN) indicated that the evidence identified on the use of nefopam for chronic pain relief was not sufficient to support a recommendation. • A Cochrane systematic review had concluded that, on the basis of small trials, there was limited evidence that nefopam and capsaicin were superior to placebo in reducing pain in patients with rheumatoid arthritis and both had significant side effects. • A Cochrane review had concluded that the use of oral nefopam in acute postoperative pain was not justified and its use for other indications needed to be evaluated. • There was some evidence about the effectiveness of nefopam in peri-operative shivering. <p>Mr Dhadli stated that a draft position statement had been produced on nefopam and this highlighted the literature search and safety considerations. It had been concluded that nefopam should be assigned a traffic light classification of BLACK as not routinely recommended or commissioned. Those patients already on treatment should be able to continue treatment until their next medication review when their NHS clinician might consider it appropriate to switch or stop treatment.</p> <p>Discussion followed and Dr Emslie highlighted that the prescribing of nefopam varied widely across the local health economy. Mr Hulme commented that a medicines management review on nefopam had been scheduled but this had now become a priority in the light of the price increase and was regarded as a drug of limited clinical value. Dr Watkins and Dr Goddard commented that nefopam did have benefit for some patients and an alternative would be needed in order to avoid patients having to take opiates with no additional benefit. Dr Mott stated that the majority of nefopam was used in primary care and it currently had a traffic light classification of BROWN. However the use of nefopam had not declined significantly, although it was not initiated before other drugs had been used, and advice would therefore need to be given to prescribers. Dr Mott also highlighted that there was a lack of capacity in the specialist pain treatment service and this had an impact on the availability of alternatives to the use of nefopam. Mr Hulme advised that nefopam should be assigned a traffic light classification of BLACK to apply to new patients and a comprehensive review undertaken on the patients who were already on nefopam. There was also a pain management guideline which referred to the non-pharmacological management of chronic non-malignant pain. Dr Henn commented that there was limited clinical evidence for other forms of pain relief such as paracetamol and codeine and some patients did derive benefit from nefopam; especially those who were intolerant of opiates. Mr Dhadli highlighted that the literature review had revealed that nefopam had not been included in national or nationally recognised guidelines.</p> <p>Agreed: Nefopam classified as a BLACK drug due to lack of data on effectiveness compared with standard therapy; lack of data on safety compared with standard therapy and less cost-effective than current standard therapy.</p>	<p style="text-align: right;">SD</p>

Item		Action
	<p>Action: The nefopam position statement would be sent for discussion to the DTHFT and CRHFT Drugs and Therapeutic Committees and for information to other Derbyshire-wide providers such as the Barlborough Treatment Centre.</p> <p>Action: The advice of the pain management consultants would be requested about how a review of those patients who were already taking nefopam could be undertaken. The comments from the two Drugs and Therapeutic Committees and the pain management consultants would be brought to the Guideline Group for further discussion and JAPC updated accordingly at a future meeting.</p>	<p style="text-align: center;">SD</p> <p style="text-align: center;">SD</p>
7.	CLINICAL GUIDELINES	
a.	<p><u>Oxygen</u> Mr Dhadli reported that the oxygen guideline was due for review in October 2016 but an extension had been requested to January 2017 when NHS England would have produced a revised home oxygen order form (HOOF) and this would be included in the guideline. The oxygen guideline has been reviewed by Claire Barnett, from the CRHFT Home Oxygen Service, and Sue Smith, Specialist Practitioner for Oxygen, CRHFT, and only minor changes made.</p> <p>Dr Henn queried whether the use of oxygen in palliative care could be reviewed and restricted as GPs were now using less oxygen in this setting due to limited evidence about effectiveness. Dr Henn added that there was some inappropriate prescribing of oxygen in primary care and a revised guideline offered an opportunity to address this. Mr Dhadli would convey the comments made by Dr Henn to the authors of the guideline before it was re-submitted for consideration by JAPC in January 2017.</p> <p>Action: JAPC ratified an extension to the oxygen guideline to January 2017.</p>	<p style="text-align: center;">SD</p> <p style="text-align: center;">SD</p>
8.	PATIENT GROUP DIRECTIONS	
a.	<p><u>PGD for Methylprednisolone Acetate 40 mg/ml for MSK</u> Mr Dhadli reported that the PGD had been submitted by Alison Hughes, from Hardwick Federation on behalf of Hardwick CCG, and aimed to improve the outcomes and expenditure relating to the treatment and management of patients with musculoskeletal (MSK) conditions, trauma and injuries in Hardwick CCG.</p> <p>Agreed: JAPC noted the PGD for Methylprednisolone Acetate 40 mg/ml for MSK.</p>	<p style="text-align: center;">SD</p>
b.	<p><u>Derbyshire Health United Patient Group Directions for Use in Out of Hours</u> Mr Dhadli reported that the omissions highlighted by JAPC at the last meeting concerning the PGDs submitted by Derbyshire Health United had now been rectified. The following revised PGDs were reviewed by JAPC:</p> <ul style="list-style-type: none"> • Amoxicillin 	

Item		Action
	<ul style="list-style-type: none"> • Codeine • Doxycycline • Erythromycin • Ibuprofen suspension • Ibuprofen tablets • Nitrofurantoin • Paracetamol suspension • Paracetamol tablets • Phenoxymethylpenicillin tablets <p>The following new PGDs were reviewed by JAPC:</p> <ul style="list-style-type: none"> • Chlorphenamine suspension • Chlorphenamine tablet • Clarithromycin • Erythromycin • Flucloxacillin • Prednisolone 5mg tablet • Salbutamol 100mcg inhaler <p>Mr Dhadli reported that a letter had been drafted by Dr Diane Harris to confirm that the PGDs were valid and accurate in terms of antibiotic use and indications. Mr Newman queried whether there was a plan for the monitoring of the antibiotics and was informed that this would need to be included in the letter drafted by Dr Harris.</p> <p>In connection with the nitrofurantoin PGD Dr Henn queried how other age groups outside the specified 16 to 65 year old age range would be covered and highlighted the inclusion of a reference to eGFR less than 60ml rather than 45ml. Mrs Needham commented that there were prescribers on site at DHU and they would be able to deal with specific issues concerning prescribing.</p> <p>Agreed: JAPC ratified all the PGDs listed above.</p>	SD
9.	HORIZON SCAN	
a.	<p><u>Monthly Horizon Scan</u> Mr Dhadli advised JAPC of the following new drug launches in the UK: Infliximab biosimilar (Flixab®) – Already classified as RED. Mercaptamine (Procysbi®) – Already classified as RED as per NHS England commissioning intentions. Pitolisant (Wakix®) – NHS England. Classified as RED. Turoctocog alfa (NovoEight®) – NHS England. Classified as RED.</p>	
b.	<p><u>NICE Horizon Scan</u> The Clinical Guidelines, NICE Technology Appraisals and NICE New Evidence Summaries were noted for information. Mr Dhadli highlighted the following are likely to be relevant to primary care prescribing or CCG commissioned high cost drugs outside tariff: Clinical Guidelines:</p>	

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	<ul style="list-style-type: none"> • Low back pain and sciatica. • Familial hypercholesterolaemia. • Asthma management. <p>NICE Technology Appraisals:</p> <ul style="list-style-type: none"> • Apremilast moderate to severe – psoriasis. • Hepatocellular carcinoma (advanced and metastatic) – sorafenib. • Cardiovascular events (reducing, high risk) – ticagrelor. • Psoriatic arthritis – certolizumab pegol and secukinumab (after DMARDs). • Chronic obstructive pulmonary disease (severe) – roflumilast. <p>Dr Mott queried whether the high cost forward planning horizon scanning process was in progress. Mr Dhadli advised that secondary high cost drugs excluded from tariff were currently being reviewed in conjunction with the DTC finance committee and Information on the primary care, secondary care and shared care drugs would be brought to a JAPC meeting together with details of budget impact.</p>	SD
10.	MISCELLANEOUS	
a.	<p><u>Prescribing Specification</u></p> <p>Mr Dhadli outlined the amendments which had been included in the updated draft version of the prescribing specification:</p> <ul style="list-style-type: none"> • Point 1 - Addition of management of conflicts of interests. • Point 18 - Clinical staff will be required to provide declarations of conflicts of interest when requesting new drugs/changes to the prescribing formulary. • Point 24 - Medication required for planned hospital procedures (for example, EMLA® cream before hospital dialysis or MRSA eradication) medication will be prescribed by the hospital/provider and treating clinician. <p>High Cost Drugs excluded from Tariff commissioned by CCGs:</p> <ul style="list-style-type: none"> • For all high cost drugs excluded from tariff the provider trust will provide patient level data for on-going quality assurance and validation. This will include the clinical criteria within the NICE technology appraisal or local policy. CCGs will conform to the information governance requirements. • For audit of high cost drugs excluded from tariff the commissioners require a minimum data set to be recorded at patient level to ensure that treatment is in line with NICE or locally agreed guidelines or policies. This will be delivered by appropriate IT software such as Blueteq. • CCGs with queries relating to HCD to the provider trust will receive a response within ten working days. • In order to allow CCGs to continue to invest in new developments we will require all Trusts to use more cost effective generic and biosimilar products where these are available and in line with product licenses. We expect Trusts to have an active improvement programme to implement use of these products with all new patients being initiated on the biosimilar/generic product within three months of them becoming available and all existing patients to have been moved to the biosimilar/ generic product within twelve months. 	

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	<p>This accelerated uptake is to reflect the urgency of efficiency savings needed to be realised within the NHS in Derbyshire. Exceptions to the 100% uptake will need to be demonstrated by provider clinicians and a threshold set and agreed at JAPC; there should be no variation of thresholds between providers.</p> <p>Mr Newman highlighted the current lack of an agreed definition of a minimum data set and the work being undertaken by NHS England to standardise the data set for use by all commissioners and providers. In addition, it was difficult for the pharmacy systems to provide diagnostic information. Mr Shepherd commented that Blueteq would provide this information but there would be cost and time implications associated with its use and an appropriate level of investment was therefore needed to assist with this. Mr Dhadli stated that the intention in the high costs section was to ensure that there was compliance with the NICE TAs as they were published and to obtain information on the number of patients involved. Dr Mott highlighted the necessity to resolve the minimum data set issue and that further information should be obtained about the work being undertaken by NHS England. Mr Dhadli would contact Susie Heathfield at NHS England to obtain further details.</p> <p>In connection with the biosimilars and gain sharing section, Mr Newman stated that there was full support for the switching of patients to a biosimilar product but advice had been given that this should not be automatically done and only then in conjunction with clinicians and patients. Mr Dhadli highlighted the inclusion in the specification of the need for the provider clinicians to demonstrate exceptions to the 100% uptake and the threshold set and agreed at JAPC; there should be no variation of thresholds between providers. It was important that the aim should always be 100% but there should be a degree of balance with this. Mr Newman also referred to the stipulated timeline in the prescribing specification and the need for an agreed plan to take account of market conditions.</p> <p>Dr Mott stated that a final document would need to have been completed for ratification by JAPC in December 2016 but in the meantime Mr Dhadli would amend the specification in the light of the comments made during the discussion. An updated version would be circulated with a request that comments be conveyed to Mr Dhadli by Tuesday, 15th November. It was suggested that a separate meeting may be needed to work through the minimum data set and biosimilar issues.</p>	<p style="text-align: center;">SD</p>
b.	<p><u>JAPC Terms of Reference</u></p> <p>The updated JAPC terms of reference were discussed and amendments made:</p> <ul style="list-style-type: none"> • Dr Parkin would remain as the link to the Research Forum. • A reference to the Working Group and Guideline Group to be added <p>Amendments to be made on the membership names.</p> <p>Agreed: JAPC ratified the terms of reference with the agreed amendments.</p>	<p style="text-align: center;">All members</p> <p style="text-align: center;">SD</p>

Item		Action
c.	<p><u>NICE Consultations</u></p> <p><u>Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE’s Technology Appraisal and Highly Specialised Technologies Programmes</u></p> <p>Mr Dhadli reported that NICE and NHS England had launched a twelve week consultation on changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE’s Technology Appraisal (TA) and Highly Specialised Technologies (HST) programmes. NICE and NHS England intend to work together more closely to better manage access to new drugs and medical technologies through the simplification and speeding up of some appraisals and by making the arrangements for funding others more clear. The importance of taking account of the financial impact when managing the introduction of new drugs and other technologies had been highlighted by the House of Commons Public Accounts Committee.</p> <p>NICE and NHS England proposed to:</p> <ul style="list-style-type: none"> • Introduce a new ‘fast track’ NICE technology appraisal process for new technologies which fell below an incremental cost-effectiveness ratio of £10,000 per QALY. Fast tracked technologies that fell below the proposed £10,000 cost per QALY level and the proposed budget impact threshold would be provided with access to NHS funding within thirty days of the publication of final NICE guidance. • Operate a ‘budget impact threshold’ of £20 million, set by NHS England, to signal the need for a dialogue with companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. • Vary the timescale for the funding requirement when the budget impact threshold was reached or exceeded, and there was therefore a compelling case that the introduction of the new technology would risk disruption to the funding of other services. • Automatically fund, from routine commissioning budgets, treatments for very rare conditions (highly specialised technologies) up to £100,000 per QALY and provide the opportunity for treatments above this range to be considered through NHS England’s process for prioritising other highly specialised technologies. <p>It was noted that the revised process would be implemented from April 2017 and the consultation would close on 13th January 2017. JAPC members were invited to individually complete the consultation questions which could be accessed online. Mr Dhadli would draft a response from JAPC and circulate this to members and also to the prescribing groups for discussion.</p> <p><u>Commissioning Medicines in Children</u></p> <p>Mr Dhadli reported that NHS England had launched a thirty day public consultation on a clinical commissioning policy proposition for commissioning medicines in children. The current position meant that patients under the age of eighteen may not be able to obtain medicines recommended under a NICE TA or HST as these covered patients over eighteen years of age. Therefore the only way they could access these treatments was via the NHS England Individual Funding (IFR) request process.</p>	<p style="text-align: center;">All members</p> <p style="text-align: center;">SD</p>

Item		Action
d.	<p>The policy proposed that NHS England would fund medicines approved in adults by a NICE TA or NHS England policy for use in children when certain conditions had been fulfilled. Mr Dhadli explained that the USA Food and Drugs Administration had developed a number of assumptions when children would be allowed to have these treatments. These assumptions were:</p> <ul style="list-style-type: none"> • There were similar disease progressions in the adult and paediatric population. • There were similar responses to the intervention in the adult and paediatric populations. • That the adult and paediatric populations had similar exposure-response relationships. <p>The following conditions would apply before a treatment could be routinely made available in the paediatric population:</p> <ul style="list-style-type: none"> • The patient met all the NICE TA/NHS England policy criteria for the proposed medicine/indication. • The patient did not meet any exclusion criteria for the medicine/indication in question. • Approval for use of the medicine had been agreed by an appropriately constructed multi-disciplinary team (MDT) at the specialised paediatric centre involving, where appropriate, the adult service. <p>It had been recommended that this policy should be adopted for use by the CCGs to achieve equity of access and it should also be discussed by the respective Trust Drugs and Therapeutic Committees and a commissioner should be in attendance at the meetings when patient cases were being discussed.</p> <p>Action: Mr Dhadli would draft a proposal for commissioning for post – pubescent children to be discussed by the CCG Policy Group. This would include the requirement for the treatment to be licensed and meet the NICE TA/NHS England criteria together with a safety and clinical efficacy process via the Trust's MDTs/DTC.</p> <p><u>Medicines Optimisation</u></p> <p>Mr Dhadli reported that a draft of the NICE medicines optimisation: key therapeutic topics document was now available. Mr Dhadli advised that there were some new indicators of multimorbidity and polypharmacy; safer insulin prescribing and asthma medicines optimisation priorities in the document. In addition, the prescribing of three-day courses of trimethoprim, nitrofurantoin and pivmecillinam had been incorporated into the antimicrobial stewardship: prescribing antibiotics section. Mr Dhadli added that the prescribing specification had been updated accordingly and advised JAPC that comments had been invited on the draft by 22nd November 2016.</p> <p><u>Nystatin and Nystan Dose Changes</u></p> <p>Mr Dhadli reported that Bristol Myers-Squibb had updated the SPCs for Nystan® however the SPCs for generic nystatin have not been updated. For Nystan® the dose had now increased to 2mls QDS for the one month to two years age group and to 4 to 6mls QDS for the >two year and adult age group.</p>	<p>SD</p> <p>All members</p>

Item		Action
e.	<p>The Nystan® pipette size remained at 1ml and the 30ml bottle size. Concern had been expressed by some UK microbiologists via their network about this change to the SPC and whether the current dosage levels should be changed. Advice had been received from a UKMI pharmacist that the origin for the dose increase appeared to be the United States of America and was also recommended in the 2016 Infectious Disease Society Clinical Practice Guidelines for the management of candidosis. The Scottish Drug Prescribing and Dentistry guideline advocated a nystatin oral suspension dose at 1ml QDS. The NICE Clinical Knowledge Summary (CKS) on candida recommended that miconazole oral gel should be the first line treatment and nystatin suspension used if miconazole was unsuitable. The NICE CKS had concluded that there was a lack of evidence from RCTs to support the effectiveness of nystatin suspension in the treatment of oral candidal infection in otherwise healthy adults. However, data extrapolated from trials in infants and immunosuppressed people suggested that it was not as effective as topical miconazole or fluconazole and therefore not suitable as a first-line treatment.</p> <p>Agreed: JAPC agreed that the current dosage be retained but would be monitored in case of any queries received.</p> <p>Action: Mr Dhadli would include a reference to the JAPC position on nystatin/Nystan® dosing in the bulletin.</p> <p><u>Pregabalin</u> Mr Dhadli reported that the Court of Appeal had ruled on 13th October 2016 calling into question the validity of the patent over pregabalin for use in pain and patent infringement. In summary most of Pfizer's patent claims regarding pain were invalid.</p> <p>Pfizer's patents for treatment of trigeminal neuralgia pain, postherpetic neuralgia, and causalgia, were still valid. It still remains unclear whether pharmacists could infringe a second-use patent by dispensing the wrong brand of pregabalin was currently undecided. It is likely that Pfizer may seek to have the NHS England pregabalin guidance on prescribing limited to prescribing Lyrica® by brand name for the claims upheld; which were neuralgia pain, postherpetic neuralgia, and causalgia.</p> <p>The generic brand price within the drug tariff remained unchanged.</p>	<p>SD</p> <p>SD</p>
f.	<p><u>Nalmefene</u> Mr Dhadli stated that the Drugs and Therapeutic Bulletin had undertaken a further review on nalmefene for the reduction of alcohol consumption in adults with alcohol dependence. DTB had concluded that the use of nalmefene could not be recommended on the basis of the evidence and subsequently three groups of researchers had highlighted several issues relating to the licensing and approval of nalmefene based on detailed reviews of published and unpublished data.</p> <p>Dr Robyn Dewis had supplied feedback from the alcohol treatment service regarding the prescribing of nalmefene in the county.</p>	

Item		Action
	<p>Since nalmefene had first been offered in August 2015 thirteen referrals had been received by the service. Five patients had been prescribed nalmefene and only one patient was currently on the drug.</p>	
11.	JAPC BULLETIN	
	<p>The JAPC bulletin was tabled for information and ratified by JAPC.</p>	SD
12.	MHRA DRUG SAFETY UPDATE	
	<p>The MHRA Drug Safety Alert for October 2016 was noted.</p> <p>Mr Dhadli highlighted the following MHRA advice:</p> <ul style="list-style-type: none"> • Etoricoxib (Arcoxia®): revised dose recommendation for rheumatoid arthritis and ankylosing spondylitis. • Letters sent to healthcare professionals in September 2016 including retigabine withdrawal. 	
13.	NICE SUMMARY	
	<p>Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in October 2016.</p> <p>TA 413 Elbasvir–grazoprevir for treating chronic hepatitis C – Classified as a RED drug (NHS England).</p> <p>TA 414 Cobimetinib in combination with vemurafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma – Classified as a BLACK drug.</p> <p>TA 415 Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor – Classified as a RED drug.</p> <p>TA 416 Osimertinib for treating locally advanced or metastatic EGFR T790M mutation positive non-small-cell lung cancer - Classified as a RED drug.</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
14.	TRAFFIC LIGHTS – ANY CHANGES?	
	<p>Classifications Nefopam – BLACK Pitolisant (Wakix®) – RED (NHS England) Turoctocog alfa (NovoEight®) – RED (NHS England) Elbasvir/grazoprevir – RED as per NICE TA 413 Cobimetinib – BLACK as per NICE TA 414 Certolizumab pegol – RED as per NICE TA 415 Osimertinib – RED as per NICE TA 416</p>	
15.	JAPC ACTION SUMMARY	
	<p>The action summary was noted by JAPC and comments and amendments made:</p> <p>PCSK9 Inhibitors – Mr Dhadli reported that Dr Roger Stanworth, DTHFT Consultant Diabetologist and Dr Paul Masters, CRHFT Consultant Diabetologist, had been liaising on the development of guidance for primary care on lipids and familial hypercholesterolemia (FH).</p>	

Item		Action
	<p>The consultants had indicated that they have patients awaiting treatment ahead of local guidance being drafted. The patients would be compliant with the NICE TA on the PCSK9 inhibitors alirocumab and evolocumab for patients with primary hypercholesterolaemia or mixed dyslipidaemia and would use the Blueteq form. It was noted that ten and fifteen patients in CRHFT and DTHFT respectively had been identified for both treatment options. Mr Dhadli added that Dr Stanworth had highlighted an equity issue concerning the need for every patient to have access to the same treatment. It would also be necessary for JAPC to review the place of rosuvastatin and ezetimibe. Mr Dhadli would contact Dr Stanworth and Dr Masters in order to confirm a date of either December or January for production of the draft PCSK9 inhibitors guidance.</p> <p>Guanfacine – To be brought to the January 2017 JAPC meeting.</p> <p>Osteoporosis – To be brought to the January 2017 JAPC meeting.</p> <p>Review of Dequalinium – To be taken off the list.</p> <p>Sayana Press – To be taken off the list.</p> <p>Sacubitril/Valsartan – To be reviewed and possibly brought to the March 2017 JAPC meeting.</p> <p>Alimemazine – To be brought to the December 2016 JAPC meeting.</p> <p>Pregnant women with neonates with measles – To be taken off the list.</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
16.	GUIDELINE GROUP ACTION TRACKER	
	<p>The summary of key messages from the Derbyshire Medicines Management Guideline Group meeting held in September 2016 was noted. Mr Dhadli highlighted the following:</p> <ul style="list-style-type: none"> • Fusidic eye drops now second line after chloramphenicol antibiotic eye ointment which was contraindicated in pregnancy. • Parkinson's Disease specialists at DTHFT and CRHFT had approved the use of Stanek® and Stalevo® over Sastravi®. Stanek® and Sastravi® now classified as GREEN drugs. The GREEN traffic light classification had been removed from Stalevo®. • NICE guidance was due to be published which would include revised hypertension targets and this would affect the timetable for the review of the existing hypertension guidelines. <p>Dr Mott highlighted the importance of ensuring that all guidelines were reviewed and updated within the stipulated timescales. In the event of delay in obtaining responses this should be escalated to JAPC.</p>	
17.	MINUTES OF OTHER PRESCRIBING GROUPS	
	<ul style="list-style-type: none"> • Sheffield Area Prescribing Group 16/06/16 • Sheffield Area Prescribing Group 21/07/16 • DHcFT Drugs and Therapeutic Committee 28/07/16 	

Item		Action
	<ul style="list-style-type: none"> • Nottinghamshire Area Prescribing Committee 21/07/16 • DTHFT (Draft) Drugs and Therapeutic Committee 16/08/16 • DTHFT Drugs and Therapeutic Committee 20/09/16 • Clinical Commissioning Policy Advisory Group 08/09/16 <p>Mr Dhadli highlighted the following from the minutes: DHcFT Drugs and Therapeutic Committee – An extension to the antipsychotic drugs guideline for a further twelve months was to be requested from JAPC but no request had been received. Mr Dhadli would contact Ms Beverley Thompson at DHCFT for this request to be made.</p>	SD
18.	ANY OTHER BUSINESS	
	There were no items of any other business.	
19.	DATE OF NEXT MEETING	
	<p>Tuesday, 13th December 2016 at 1.30pm in the Post Mill Centre, South Normanton.</p> <p>Dates of the JAPC meetings in 2017 were noted: 10 January 14 February 14 March 11 April 9 May 13 June 11 July 8 August 12 September 10 October 14 November 12 December</p>	